

US3042209 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:52:12

All time stamps listed in this document are displayed in GMT

US3042209

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

[Participant ID](#)

US3042209

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Apr 2021 15:16:21

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Date of Informed Consent (<i>dd MMM yyyy</i>)	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 15:16:21

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 15:16:22

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 15:16:22

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Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Condition	OBESITY
Start date (dd MMM yyyy)	UN APR 2020
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)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:05 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 16:05
Height (<i>xxx.x</i>)	163.8 cm
Weight (<i>xxx.x</i>)	86.5 kg
BMI (<i>xxx.x</i>)	32.23950 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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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Form: Childbearing Potential

Data signed: (b) (4) 28 Apr 2021 15:16:21

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Date of assessment (dd MMM yyyy) 14 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 15:16:22

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	14 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 15:16:22

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 15:16:22

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 15:16:22

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What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 144035

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 15:16:22

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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) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

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)	14 AUG 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 16:05
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	17:30 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 17:30
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 15:16:22

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Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

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) 14 AUG 2020

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

Treatment Date and Time (derived) 14 AUG 2020 16:54

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	16:42 (24 HR)
Collection date and time (derived)	14 AUG 2020 16:42

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:31	14 AUG 2020 16:31
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

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 21:52:12

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 17:14

PC Open Date & Time

14 AUG 2020 17:14

PC Close Date & Time

14 AUG 2020 19:44

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

PC Time Stamp	14 AUG 2020 21:05
PC Open Date & Time	14 AUG 2020 20:39
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:11

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 13:49

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:11

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 12:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 12:07

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:01

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

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

14 AUG 2020 17:15

PC Open Date & Time

14 AUG 2020 17:14

PC Close Date & Time

14 AUG 2020 19:44

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

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

14 AUG 2020 21:05

PC Open Date & Time

14 AUG 2020 20:39

PC Close Date & Time

15 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:10

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

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

16 AUG 2020 13:49

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

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

17 AUG 2020 12:11

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

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

18 AUG 2020 12:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

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

19 AUG 2020 12:08

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

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

20 AUG 2020 12:01

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 17:15
PC Open Date & Time	14 AUG 2020 17:14
PC Close Date & Time	14 AUG 2020 19:44

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 21:05
PC Open Date & Time	14 AUG 2020 20:39
PC Close Date & Time	15 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

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 ☒

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 13:49
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

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 ☒

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

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 ☒

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:01
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

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 ☒

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:08
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

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 ☒

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:01
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3042209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3042209

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3042209

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

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	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3042209

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3042209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

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?

US3042209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3042209

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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 _____

US3042209

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:38 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 15:38
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042209

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3042209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 OCT 2020
Collection time (00:00-23:59)	15:50 (24 HR)
Collection date and time (derived)	20 OCT 2020 15:50

US3042209

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 OCT 2020 14:11:49
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

21 OCT 2020 00:47:27

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

28 OCT 2020 01:51:51

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 03:35:49
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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	18 NOV 2020 06:00:49
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 03:09:25

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 08:19:10

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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	13 DEC 2020 00:22:39
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

20 DEC 2020 00:02:39

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 05:53:22

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 00:39:34

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 00:34:34

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 12:15:09

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 12:46:06

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 06:59:20

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 19:49:17
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 17:52:26
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 10:18:41
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 14:12:08
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 07:19:00

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 23:30:43

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 06:54:49

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 01:58:21

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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	04 APR 2021 03:18:45
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

12 APR 2021 12:35:18

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 11:19:56

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

27 APR 2021 08:27:45

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

03 MAY 2021 08:09:52

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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°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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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="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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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="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°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="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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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="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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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="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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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="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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	20 JAN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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°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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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17 MAR 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 APR 2022 00:01

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07 APR 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 APR 2022 00:01

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14 APR 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 APR 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 APR 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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°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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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05 MAY 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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12 MAY 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

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19 MAY 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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26 MAY 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

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02 JUN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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°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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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14 JUL 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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28 JUL 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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04 AUG 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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="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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 <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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3042209

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:52:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 14:12:15

US3042209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3042209

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042209

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042209

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042209

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

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) _____

US3042209

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3042209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 FEB 2021
Collection time (00:00-23:59)	13:57 (24 HR)
Collection date and time (derived)	26 FEB 2021 13:57

US3042209

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:22

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3042209

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Date of Contact	08 SEP 2020
Time of Contact	00:00
Date and Time of Contact (derived)	08 SEP 2020 00:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Symptom Day

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.9 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Symptom Day

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 (2)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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 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 (3)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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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Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 (10)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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EAB) (1725)

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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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"/>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (12)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 (13)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 (13)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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"/>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 (14)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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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EAB) (1725)

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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Symptom Day

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 15:15:38

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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	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (19)

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	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 08 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 15:15:38

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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 08 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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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Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (20)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 08 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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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Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (21)

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Generated On: 11 Aug 2021 21:52:12

	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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Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 15:15:38

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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 (22)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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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Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Generated On: 11 Aug 2021 21:52:12

	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"/>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (23)

Data signed: (b) (4) 28 Apr 2021 15:15:38

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	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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EAB) (1725)

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

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EAB) (1725)

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US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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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US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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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EAB) (1725)

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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"/>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 08 Sep 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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"/>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

	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"/>

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Date of Visit	08 SEP 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	08 SEP 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 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	10 SEP 2020
Day 5	Yes	12 SEP 2020
Day 7	Yes	14 SEP 2020
Day 9	Yes	16 SEP 2020
Day 14	Yes	21 SEP 2020
Day 21	No	
Day 28	Yes	06 OCT 2020

US3042209

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 11 Aug 2021 21:52:12

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3042209

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

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	SICKD1

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	17:14 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 17:14
Height (<i>xxx.x</i>)	163.83 cm
Weight (<i>xxx.x</i>)	86.0 kg
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042209

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

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.

US3042209

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 SEP 2020

US3042209

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3042209

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3042209

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:52:12

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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	SICKD28

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	07:55 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 07:55
Height (xxx.x)	163.83 cm
Weight (xxx.x)	86.4 kg
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3042209

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

06 OCT 2020

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3042209

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:52:12

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3042209

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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

Visit date (dd MMM yyyy)	11 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	UNBLND_DECIDE
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US3042209

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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

US3042209

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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

US3042209

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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 MAR 2021
Time of assessment (00:00-23:59)	18:15 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 18:15
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3042209

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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 MAR 2021
Time of assessment (00:00-23:59)	19:38 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 19:38
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3042209

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3042209

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

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 11 MAR 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3042209

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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 MAR 2021

What was the treatment time? (00:00-23:59) 19:04 (24 HR)

Treatment Date and Time (derived) 11 MAR 2021 19:04

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

US3042209

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 MAR 2021
Collection time (<i>00:00-23:59</i>)	18:25 (24 HR)
Collection date and time (derived)	11 MAR 2021 18:25

US3042209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00 - 23:59)	18:37
Collection Date and Time (derived)	11 MAR 2021 18:37

US3042209

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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

US3042209

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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)	12 APR 2021
Time of assessment (00:00-23:59)	16:21 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 16:21
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

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)	12 APR 2021
Time of assessment (00:00-23:59)	17:00 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 17:00
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3042209

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	12 APR 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3042209

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

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) 12 APR 2021

What was the treatment time? (00:00-23:59) 16:30 (24 HR)

Treatment Date and Time (derived) 12 APR 2021 16:30

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

US3042209

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042209

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042209

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3042209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3042209

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3042209

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3042209

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3042209

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

AEID	USA-US052-2020-MRNA-1273-P30 1000005
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)	08 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 OCT 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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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

AEID

Adverse event

ACUTE BACTERIAL SINUSITIS

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)

18 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 15:15:37

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

AEID

Adverse event

SOFT TISSUE INJURY-LEFT
SHOULDER

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)

01 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

09 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 15:15:37

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication PHENTERMINE

Prophylaxis Yes ☐
No ☒

Indication OBESITY

Dose per administration 37.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 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 (2)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication LARIN FE 1/20

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 1/0.02

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) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 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 (4)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication MEFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication JAURDIANCE

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 15:15:37

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication AMARYL

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication PROPRANLOL

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 120

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) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication RIZATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

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 (8)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	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 JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication RYBELSUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	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)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input 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"/>

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication AUGMENTIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE BACTERIAL 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 ☐
Intraocular ☐

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US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 SEP 2020		
Was this medication taken for solicited event?	Yes	<input 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication	TRAMADOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LEFT SHOULDER SOFT TISSUE INJURY
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	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)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication LEFT SHOULDER SOFT TISSUE
INJURY

Dose per administration 750

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 (13)

Data signed: (b) (4) 28 Apr 2021 15:15:37

Generated On: 11 Aug 2021 21:52:12

	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)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3042209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 15:15:38

Generated On: 11 Aug 2021 21:52:12

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 28 Apr 2021 15:15:39

Generated On: 11 Aug 2021 21:52:12

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	True
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	True
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	True
Physical Examination	True
Central Laboratory - Nasopharyngeal Swab	True
Childbearing Potential	False
Pregnancy Test	True
Randomization	False
Exposure	True
Immunogenicity Assessment	True
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 28 Apr 2021 15:15:39

Generated On: 11 Aug 2021 21:52:12

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	01 SEP 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	True
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	True
Possible exposure to COVID-19	False
Exposure to COVID-19	True
Presumption / confirmed COVID-19	False
Symptoms of COVID-19	True
Sponsor hold due to COVID-19	False
Participant decision	False

US3042209

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Apr 2021 15:15:40

Generated On: 11 Aug 2021 21:52:12

Date of dosing discontinuation (dd MMM yyyy) 08 SEP 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

US3042209

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:12

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 ☐

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

SAEID	USA-US052-2020-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

SAEID	USA-US052-2020-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/SEP/2020 14:14
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

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

SAEID	USA-US052-2020-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/SEP/2020 12:25
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

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

SAEID	USA-US052-2020-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/SEP/2020 11:09
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

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

SAEID	USA-US052-2020-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/SEP/2020 14:57
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

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

SAEID	USA-US052-2020-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/OCT/2020 19:26
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

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

SAEID	USA-US052-2020-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/OCT/2020 19:36
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

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 15:16:21

Generated On: 11 Aug 2021 21:52:12

SAEID	USA-US052-2020-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:45
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

US3042209 (Prod: Meridian Clinical Research)

US3042209

Form: Participant Creation

Generated On: 11 Aug 2021 21:52:12

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:15:40
User entered 'US3042209'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 21:49:09

US3042209

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:06
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:14:39

US3042209

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:06
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 21:49:11

US3042209

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:06
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:14:39

US3042209

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'SCRN'	(b) (4), (b) (6) System	15 Aug 2020 14:14:39

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered (b) (6) 1989'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 21:49:12

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered '30'	Rylea Gulick (b) (4)	15 Aug 2020 14:16:05
	(b) (4)	

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'YEARS'	(b) (4), (b) (6) System	15 Aug 2020 14:16:05

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered '30'	(b) (4), (b) (6) System	14 Aug 2020 21:58:23

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered 'Female (F)'	Rylea Gulick (b) (4)	15 Aug 2020 14:16:05
	(b) (4)	

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:16:05

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:16:05

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 14:16:05
	(b) (4)	

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 14:16:05
	(b) (4)	

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 14:16:05
	(b) (4)	

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:16:05

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 14:16:05
	(b) (4)	

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 14:16:05
	(b) (4)	

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:16:05

US3042209

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:43
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 14:16:05
	(b) (4)	

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:55
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:23
	(b) (4)	

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'Aug 2020'	(b) (4), (b) (6) System	14 Aug 2020 21:58:23

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered '2020'	(b) (4), (b) (6) System	14 Aug 2020 21:58:23

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:55
User entered 'Amendment 2 (2)'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:23
	(b) (4)	

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:23
	(b) (4)	

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:05:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 21:58:23

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:55
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 21:58:23
	(b) (4)	

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:55
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:23
	(b) (4)	

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 21:49:11

US3042209

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered '1'	(b) (4), (b) (6) System	14 Aug 2020 21:58:24

US3042209

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:06:31
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:24
	(b) (4)	

US3042209

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:52:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:06:38
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:16:18

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:18:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:18:20
Data point term sent to Coder	System	15 Aug 2020 14:17:23
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered 'UN UNK 2013'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'Jan 2013'	(b) (4), (b) (6) System	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered '2013'	(b) (4), (b) (6) System	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 14:17:03

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:18:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:18:20
Data point term sent to Coder	System	15 Aug 2020 14:17:23
User entered 'MIGRAINE HEADACHES'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered 'UN UNK 2013'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'Jan 2013'	(b) (4), (b) (6) System	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered '2013'	(b) (4), (b) (6) System	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 14:17:18

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:19:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:19:20
Data point term sent to Coder	System	15 Aug 2020 14:18:26
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered 'UN UNK 2018'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered '2018'	(b) (4), (b) (6) System	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 14:17:25

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:36:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:36:45
Data point term sent to Coder	System	02 Oct 2020 19:35:40
User entered 'obesity'	Meagan Miller (b) (4)	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered 'un Apr 2020'	Meagan Miller (b) (4)	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered '0'	Meagan Miller (b) (4)	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered 'Yes (Y)'	Meagan Miller (b) (4)	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered empty.	Meagan Miller (b) (4)	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:21
User entered '0'	Meagan Miller (b) (4)	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'Apr 2020'	(b) (4), (b) (6) System	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered '2020'	(b) (4), (b) (6) System	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered empty.	(b) (4), (b) (6) System	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered empty.	(b) (4), (b) (6) System	02 Oct 2020 19:35:09

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered '16:05'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered '14 Aug 2020 16:05'	(b) (4), (b) (6) System	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered '163.8' cm	Rylea Gulick (b) (4)	15 Aug 2020 14:18:03
DataPoint set to visible.	(b) (4) System	14 Aug 2020 21:58:24

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered '86.5' kg	Rylea Gulick (b) (4)	15 Aug 2020 14:18:03
DataPoint set to visible.	(b) (4) System	14 Aug 2020 21:58:24

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
Amendment Manager: User entered '32.23950'	(b) (4), (b) (6)	
	System	16 Sep 2020 23:58:12
User entered '32.2'	System	15 Aug 2020 14:18:03
DataPoint set to visible.	System	14 Aug 2020 21:58:24

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'kg/m2'	(b) (4), (b) (6)	15 Aug 2020 14:18:03
DataPoint set to visible.	System	14 Aug 2020 21:58:24

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User closed query 'Per CDM : Kindly remove the unit for temperature, Thanks' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:59:55
Query 'Per CDM : Kindly remove the unit for temperature, Thanks' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	09 Oct 2020 16:15:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Oct 2020 16:15:48
User opened query 'Per CDM : Kindly remove the unit for temperature, Thanks' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:03:13
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:03:13
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:26:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:28

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM). User entered '36.4' C	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 08:15:21 15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:28
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User closed query 'Per CDM: Thanks for the response, kindly Remove units for PULSE, RESPIRATORY RATE, SYS BP and DIA BP as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:05:48
Query 'Per CDM: Thanks for the response, kindly Remove units for PULSE, RESPIRATORY RATE, SYS BP and DIA BP as well. Please update accordingly.' answered with 'unable to remove units (beats/min; mmHg) are in automatically' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Nov 2020 18:59:08
User opened query 'Per CDM: Thanks for the response, kindly Remove units for PULSE, RESPIRATORY RATE, SYS BP and DIA BP as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:40:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:28
User entered '99'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:28
User entered '12'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:28
User entered '119'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:28
User entered '95'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 14:18:03

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:02

US3042209

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:35:02

US3042209

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:49
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:07

US3042209

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:49
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:49:12
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		09 Sep 2020 00:16:08
User entered '14 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:07

US3042209

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:58
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:12

US3042209

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:12

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:07:58
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 14:18:12
	(b) (4)	

US3042209

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:12

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:07:58
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 14:18:12
	(b) (4)	

US3042209

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:12

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:58
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:12

US3042209

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:12

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:12

US3042209

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:12

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:12

US3042209

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:58
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:12

US3042209

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:12

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:12

US3042209

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:14
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:29

US3042209

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:14
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:29

US3042209

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:08:14
User entered 'Urine (URINE)'	Rylea Gulick (b) (4)	15 Aug 2020 14:18:29
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:14
User entered 'Negative (NEGATIVE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:29

US3042209

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:08:14
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 14:18:29
	(b) (4)	

US3042209

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:14
User closed query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed,Kindly confirm if the FSH collected is Yes/NO, If NO, kindly remove the date and time. Thanks ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:53:48
Query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed,Kindly confirm if the FSH collected is Yes/NO, If NO, kindly remove the date and time. Thanks ' answered with 'Corrected' (Site from DM).	Meagan Miller (b) (4)	10 Sep 2020 22:12:47
User entered empty; reason for change Data Entry Error	Meagan Miller (b) (4)	10 Sep 2020 22:12:43
User opened query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed,Kindly confirm if the FSH collected is Yes/NO, If NO, kindly remove the date and time. Thanks ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:29:46
User entered '14 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:18:29

US3042209

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:08:14
User entered empty; reason for change Data Entry Error	Meagan Millert (b) (4)	10 Sep 2020 22:12:43
User entered '16:15'	Rylea Gulickt (b) (4)	15 Aug 2020 14:18:29
	(b) (4)	

US3042209

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
	(b) (4), (b) (6)	
User entered empty.	System	10 Sep 2020 22:12:43
User entered '14 Aug 2020 16:15'	System	15 Aug 2020 14:18:29

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:35:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:08:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:05

US3042209

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:23
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 14:19:15
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:23
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 14:19:15
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:23
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	15 Aug 2020 14:19:15
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'VISIT1'	(b) (4), (b) (6) System	15 Aug 2020 14:19:15

US3042209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:33
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 21:49:16

US3042209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:44:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:44:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 21:49:16
User entered '144035' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 21:49:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:33
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 21:49:16

US3042209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

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)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:33
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:23

US3042209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

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)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:33
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:19:23

US3042209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:33
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 14:19:23
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:33
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 14:19:23
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:33
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 14:19:23
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:33
	(b) (4), (b) (6)	
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:40:15
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4)	29 Oct 2020 17:40:46
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	29 Oct 2020 17:40:42
	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:29:30
	(b) (4), (b) (6)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:40
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:25:59

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:43:34
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:07
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:51:42
User entered '163.8' cm	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:41:07
	(b) (4)	
User entered '86.5' kg	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:43:34
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:10
answered with 'ENTRY UPDATED' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:07
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:51:42
User entered '163.8' cm	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:41:07
	(b) (4)	
User entered '86.5' kg	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '16:05'		
	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '14 Aug 2020 16:05'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '36.4' C	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '119'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '95'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:43:34
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:41:07
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:51:42
User entered '163.8' cm	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:41:07
	(b) (4)	
User entered '86.5' kg	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 07:39:51
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'PER PROTOCOL, SUBJECT ONLY NEEDS TO WAIT 30 MINUTES AFTER VACCINATION BEFORE POST DOSE VITALS ARE TAKEN' (Site from System).	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:55
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		15 Aug 2020 14:20:27
User entered '17:30'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '14 Aug 2020 17:30'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '36.9' C		
	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '98'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '12'	Rylea Gulick (b) (4)	15 Aug 2020 14:20:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '112'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:09:50
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 14:20:27

US3042209

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:10:08
User closed query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:50:25
Query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:20:20
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:20:16
User opened query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:28:07
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:21:02

US3042209

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:08
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	06 Nov 2020 17:20:16
	(b) (4)	
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 14:21:02
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:10:17
User closed query 'Per CDM please note as Screening and Visit 1 is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 04:15:15
Query 'Per CDM please note as Screening and Visit 1 is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' answered with 'Corrected' (Site from DM).	Meagan Miller (b) (4)	10 Sep 2020 22:08:44
User entered 'No (N)' reason for change: Data Entry Error	Meagan Miller (b) (4)	10 Sep 2020 22:08:34
User opened query 'Per CDM please note as Screening and Visit 1 is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:30:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:21:29

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:17
User entered empty; reason for change Data Entry Error	Meagan Miller (b) (4)	10 Sep 2020 22:08:34
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 14:21:29
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:17
User entered empty; reason for change Data Entry Error	Meagan Miller (b) (4)	10 Sep 2020 22:08:34
User entered 'Urine (URINE)'	Rylea Gulick (b) (4)	15 Aug 2020 14:21:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:17
User entered empty; reason for change Data Entry Error	Meagan Miller (b) (4)	10 Sep 2020 22:08:34
User entered 'Negative (NEGATIVE)'	Rylea Gulick (b) (4)	15 Aug 2020 14:21:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:10:17
User closed query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:42:13
Query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	26 Oct 2020 17:15:17
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	26 Oct 2020 17:15:14
User opened query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:02:55
User entered empty; reason for change Data Entry Error	Meagan Miller (b) (4)	10 Sep 2020 22:08:34
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:21:29

US3042209

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:10:17
User entered empty; reason for change Data Entry Error	Meagan Miller (b) (4)	10 Sep 2020 22:08:34
Query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed.The urine test time need not be filled in this field, this field is for FSH sample collection.As per the response the FSH collected is NO, kindly remove the date and time. Kindly correct.' canceled (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:30:23
User opened query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed.The urine test time need not be filled in this field, this field is for FSH sample collection.As per the response the FSH collected is NO, kindly remove the date and time. Kindly correct.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 04:10:37
User closed query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 04:10:37
Query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' answered with 'No FSH collected; time is for urine pregnancy test.' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	29 Aug 2020 18:06:13
User opened query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 09:44:57
User entered '14 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:21:29

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:17
User entered empty; reason for change Data Entry Error	Meagan Miller (b) (4)	10 Sep 2020 22:08:34
User entered '16:15'	Rylea Gulick (b) (4)	15 Aug 2020 14:21:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered empty.	(b) (4), (b) (6)	
	System	10 Sep 2020 22:08:34
User entered '14 Aug 2020 16:15'	System	15 Aug 2020 14:21:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:29
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:29
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 21:58:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:10:29
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 21:58:39

US3042209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:29
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:39
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:29
User entered '16:54'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:39
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '14 Aug 2020 16:54'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:29
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	14 Aug 2020 21:58:39
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:29
User entered 'ONCE'	System	14 Aug 2020 21:58:39

US3042209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:10:46
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:21:51

US3042209

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:46
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 14:21:51
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:10:46
User entered '16:42'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:21:51

US3042209

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '14 Aug 2020 16:42'	(b) (4), (b) (6) System	15 Aug 2020 14:21:51

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:52:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:56
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 14:22:05
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	15 Aug 2020 14:22:05

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:56
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 14:22:05
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:10:56
User entered '16:31'		
	Rylea Gulick (b) (4)	15 Aug 2020 14:22:05
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '14 Aug 2020 16:31'	(b) (4), (b) (6) System	15 Aug 2020 14:22:05

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Rylea Gulick (b) (4)	15 Aug 2020 14:22:05

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:10:56
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:05

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:10:56
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 14:22:05
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 14:22:05

US3042209

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:11:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 14:22:07
	(b) (4)	

US3042209

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:53:31
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 14:22:07

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:14:29', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '1d8a2071-0149-4d19-a316-c6e504625797'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	14 Aug 2020 22:14:41

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:14:33', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '1d8a2071-0149-4d19-a316-c6e504625797' User entered '98.4'	(b) (4), (b) (6) System	14 Aug 2020 22:14:41
	System	14 Aug 2020 22:14:41

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:14:36', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '1d8a2071-0149-4d19-a316-c6e504625797'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Aug 2020 22:14:41

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:14:40', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '1d8a2071-0149-4d19-a316-c6e504625797'	(b) (4), (b) (6)	
User entered '14 Aug 2020 17:14'	System	14 Aug 2020 22:14:41

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 17:14'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 19:44'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:04:57', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bbc95260-0f75-4e16-800b-7223905fbe24' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:10
	System	15 Aug 2020 02:05:10

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:02', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bbc95260-0f75-4e16-800b-7223905fbe24' User entered '98.9'	(b) (4), (b) (6) System	15 Aug 2020 02:05:10
	System	15 Aug 2020 02:05:10

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:04', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bbc95260-0f75-4e16-800b-7223905fbe24'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Aug 2020 02:05:10

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:07', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bbc95260-0f75-4e16-800b-7223905fbe24' User entered '14 Aug 2020 21:05'	(b) (4), (b) (6) System	15 Aug 2020 02:05:10
	System	15 Aug 2020 02:05:10

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 20:39'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 2'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:11:08', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '848ee740-a160-45e0-9b35-74701668883f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:22
	System	15 Aug 2020 17:11:22

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:11:12', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '848ee740-a160-45e0-9b35-74701668883f' User entered '97.6'	(b) (4), (b) (6) System	15 Aug 2020 17:11:22
	System	15 Aug 2020 17:11:22

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:11:14', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '848ee740-a160-45e0-9b35-74701668883f' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:22
	System	15 Aug 2020 17:11:22

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:11:16', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '848ee740-a160-45e0-9b35-74701668883f' User entered '15 Aug 2020 12:11'	(b) (4), (b) (6) System	15 Aug 2020 17:11:22
	System	15 Aug 2020 17:11:22

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 3'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:20', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e30b7379-5a47-4694-844f-0f32363abe77'	(b) (4), (b) (6)	
	System	16 Aug 2020 18:49:32
User entered 'Yes (Y)'	System	16 Aug 2020 18:49:32

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:24', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e30b7379-5a47-4694-844f-0f32363abe77' User entered '98.3'	(b) (4), (b) (6) System	16 Aug 2020 18:49:32
	System	16 Aug 2020 18:49:32

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:27', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e30b7379-5a47-4694-844f-0f32363abe77'	(b) (4), (b) (6)	
	System	16 Aug 2020 18:49:32
User entered 'No (N)'	System	16 Aug 2020 18:49:32

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:30', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e30b7379-5a47-4694-844f-0f32363abe77' User entered '16 Aug 2020 13:49'	(b) (4), (b) (6) System	16 Aug 2020 18:49:32
	System	16 Aug 2020 18:49:32

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 4'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:10:40', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '52fa2142-874a-4185-ad16-de5965a90067' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Aug 2020 17:11:12
	System	17 Aug 2020 17:11:12

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:10:44', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '52fa2142-874a-4185-ad16-de5965a90067' User entered '98.1'	(b) (4), (b) (6) System	17 Aug 2020 17:11:12
	System	17 Aug 2020 17:11:12

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:07', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '52fa2142-874a-4185-ad16-de5965a90067' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 17:11:12
	System	17 Aug 2020 17:11:12

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:10', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '52fa2142-874a-4185-ad16-de5965a90067' User entered '17 Aug 2020 12:11'	(b) (4), (b) (6) System	17 Aug 2020 17:11:12
	System	17 Aug 2020 17:11:12

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 5'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:17', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'c3c1d543-e430-4503-8f8b-2e48f25a30aa' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Aug 2020 17:02:09
	System	18 Aug 2020 17:02:09

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:21', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'c3c1d543-e430-4503-8f8b-2e48f25a30aa' User entered '97.9'	(b) (4), (b) (6) System	18 Aug 2020 17:02:09
	System	18 Aug 2020 17:02:09

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:23', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'c3c1d543-e430-4503-8f8b-2e48f25a30aa'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Aug 2020 17:02:09

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:25', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'c3c1d543-e430-4503-8f8b-2e48f25a30aa' User entered '18 Aug 2020 12:01'	(b) (4), (b) (6) System	18 Aug 2020 17:02:09
	System	18 Aug 2020 17:02:09

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 6'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:32', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '23f88df7-dd76-4787-a6ef-c007b8e82848' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Aug 2020 17:07:46
	System	19 Aug 2020 17:07:46

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:38', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '23f88df7-dd76-4787-a6ef-c007b8e82848' User entered '97.9'	(b) (4), (b) (6) System	19 Aug 2020 17:07:46
	System	19 Aug 2020 17:07:46

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:42', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '23f88df7-dd76-4787-a6ef-c007b8e82848'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Aug 2020 17:07:46

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:44', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '23f88df7-dd76-4787-a6ef-c007b8e82848' User entered '19 Aug 2020 12:07'	(b) (4), (b) (6) System	19 Aug 2020 17:07:46
	System	19 Aug 2020 17:07:46

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 7'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:05', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'aa5321f7-b7dc-46d6-9dc3-f035b54a73a8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:40
	System	20 Aug 2020 17:01:40

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:10', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'aa5321f7-b7dc-46d6-9dc3-f035b54a73a8' User entered '98.1'	(b) (4), (b) (6) System	20 Aug 2020 17:01:40
	System	20 Aug 2020 17:01:40

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:12', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'aa5321f7-b7dc-46d6-9dc3-f035b54a73a8' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:40
	System	20 Aug 2020 17:01:40

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:14', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'aa5321f7-b7dc-46d6-9dc3-f035b54a73a8' User entered '20 Aug 2020 12:01'	(b) (4), (b) (6) System	20 Aug 2020 17:01:40
	System	20 Aug 2020 17:01:40

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:10', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '3b3b1f3a-f147-4f9c-bae0-498b6b99f55d' User entered 'Does not interfere with activity (2)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:23
	System	14 Aug 2020 22:15:23

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:13', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '3b3b1f3a-f147-4f9c-bae0-498b6b99f55d' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:23
	System	14 Aug 2020 22:15:23

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:14', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '3b3b1f3a-f147-4f9c-bae0-498b6b99f55d' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:23
	System	14 Aug 2020 22:15:23

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:19', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '3b3b1f3a-f147-4f9c-bae0-498b6b99f55d' User entered 'None (1)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:23
	System	14 Aug 2020 22:15:23

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:22', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '3b3b1f3a-f147-4f9c-bae0-498b6b99f55d' User entered '14 Aug 2020 17:15'	(b) (4), (b) (6) System	14 Aug 2020 22:15:23
	System	14 Aug 2020 22:15:23

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 17:14'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 19:44'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:10', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '58a2dad2-f294-417c-bf21-1091d3a3a1f2' User entered 'None (1)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:22
	System	15 Aug 2020 02:05:22

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:12', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '58a2dad2-f294-417c-bf21-1091d3a3a1f2' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:22
	System	15 Aug 2020 02:05:22

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:14', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '58a2dad2-f294-417c-bf21-1091d3a3a1f2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Aug 2020 02:05:22

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:16', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '58a2dad2-f294-417c-bf21-1091d3a3a1f2' User entered 'None (1)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:22
	System	15 Aug 2020 02:05:22

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:19', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '58a2dad2-f294-417c-bf21-1091d3a3a1f2'	(b) (4), (b) (6)	
	System	15 Aug 2020 02:05:22
User entered '14 Aug 2020 21:05'	System	15 Aug 2020 02:05:22

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 20:39'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 2'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:34', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e323940c-9122-40f1-8a54-b755babfca4e' User entered 'None (1)'	(b) (4), (b) (6) System	15 Aug 2020 17:10:44
	System	15 Aug 2020 17:10:44

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:36', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e323940c-9122-40f1-8a54-b755babfca4e' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 17:10:44
	System	15 Aug 2020 17:10:44

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:38', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e323940c-9122-40f1-8a54-b755babfca4e' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 17:10:44
	System	15 Aug 2020 17:10:44

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:40', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e323940c-9122-40f1-8a54-b755babfca4e' User entered 'None (1)'	(b) (4), (b) (6) System	15 Aug 2020 17:10:44
	System	15 Aug 2020 17:10:44

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:42', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e323940c-9122-40f1-8a54-b755babfca4e' User entered '15 Aug 2020 12:10'	(b) (4), (b) (6) System	15 Aug 2020 17:10:44
	System	15 Aug 2020 17:10:44

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 3'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:45', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'a3887c51-3f0d-4bdd-b7f3-7131fd0b2ddc' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 18:50:01
	System	16 Aug 2020 18:50:01

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:48', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'a3887c51-3f0d-4bdd-b7f3-7131fd0b2ddc' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 18:50:01
	System	16 Aug 2020 18:50:01

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:49', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'a3887c51-3f0d-4bdd-b7f3-7131fd0b2ddc' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 18:50:01
	System	16 Aug 2020 18:50:01

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:51', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'a3887c51-3f0d-4bdd-b7f3-7131fd0b2ddc' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 18:50:01
	System	16 Aug 2020 18:50:01

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:59', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'a3887c51-3f0d-4bdd-b7f3-7131fd0b2ddc' User entered '16 Aug 2020 13:49'	(b) (4), (b) (6) System	16 Aug 2020 18:50:01
	System	16 Aug 2020 18:50:01

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 4'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:13', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '45da98c0-27d4-40a6-b49a-002a99d695e1' User entered 'None (1)'	(b) (4), (b) (6) System	17 Aug 2020 17:12:17
	System	17 Aug 2020 17:12:17

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:15', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '45da98c0-27d4-40a6-b49a-002a99d695e1' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 17:12:17
	System	17 Aug 2020 17:12:17

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:20', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '45da98c0-27d4-40a6-b49a-002a99d695e1' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 17:12:17
	System	17 Aug 2020 17:12:17

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:21', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '45da98c0-27d4-40a6-b49a-002a99d695e1' User entered 'None (1)'	(b) (4), (b) (6) System	17 Aug 2020 17:12:17
	System	17 Aug 2020 17:12:17

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:23', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '45da98c0-27d4-40a6-b49a-002a99d695e1' User entered '17 Aug 2020 12:11'	(b) (4), (b) (6) System	17 Aug 2020 17:12:17
	System	17 Aug 2020 17:12:17

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 5'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:28', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4f042837-75ba-4bae-982d-00458afdc9f5'	(b) (4), (b) (6)	
	System	18 Aug 2020 17:02:14
User entered 'None (1)'	System	18 Aug 2020 17:02:14

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:30', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4f042837-75ba-4bae-982d-00458afdc9f5'	(b) (4), (b) (6)	
	System	18 Aug 2020 17:02:14
User entered 'No (N)'	System	18 Aug 2020 17:02:14

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:31', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4f042837-75ba-4bae-982d-00458afdc9f5'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Aug 2020 17:02:14

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:32', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4f042837-75ba-4bae-982d-00458afdc9f5'	(b) (4), (b) (6)	
	System	18 Aug 2020 17:02:14
User entered 'None (1)'	System	18 Aug 2020 17:02:14

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:34', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4f042837-75ba-4bae-982d-00458afdc9f5' User entered '18 Aug 2020 12:01'	(b) (4), (b) (6) System	18 Aug 2020 17:02:14
	System	18 Aug 2020 17:02:14

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 6'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:08:05', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'f37d98ea-a414-4a08-bf13-6e98e04235ac' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:16
	System	19 Aug 2020 17:08:16

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:08:08', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'f37d98ea-a414-4a08-bf13-6e98e04235ac' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:16
	System	19 Aug 2020 17:08:16

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:08:10', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'f37d98ea-a414-4a08-bf13-6e98e04235ac' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:16
	System	19 Aug 2020 17:08:16

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:08:11', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'f37d98ea-a414-4a08-bf13-6e98e04235ac' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:16
	System	19 Aug 2020 17:08:16

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:08:14', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'f37d98ea-a414-4a08-bf13-6e98e04235ac' User entered '19 Aug 2020 12:08'	(b) (4), (b) (6) System	19 Aug 2020 17:08:16
	System	19 Aug 2020 17:08:16

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 7'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:37', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '6ed2607a-0dc3-4de9-ad5c-5bc5a6d7ecae' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:55
	System	20 Aug 2020 17:01:55

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:39', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '6ed2607a-0dc3-4de9-ad5c-5bc5a6d7ecae' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:55
	System	20 Aug 2020 17:01:55

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:41', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '6ed2607a-0dc3-4de9-ad5c-5bc5a6d7ecae' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:55
	System	20 Aug 2020 17:01:55

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:42', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '6ed2607a-0dc3-4de9-ad5c-5bc5a6d7ecae' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:55
	System	20 Aug 2020 17:01:55

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:45', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '6ed2607a-0dc3-4de9-ad5c-5bc5a6d7ecae' User entered '20 Aug 2020 12:01'	(b) (4), (b) (6) System	20 Aug 2020 17:01:55
	System	20 Aug 2020 17:01:55

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:27', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b2d26f09-7167-4a9f-bcd7-b27d932e8523' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:49
	System	14 Aug 2020 22:15:49

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:28', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b2d26f09-7167-4a9f-bcd7-b27d932e8523' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:49
	System	14 Aug 2020 22:15:49

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:31', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b2d26f09-7167-4a9f-bcd7-b27d932e8523' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:49
	System	14 Aug 2020 22:15:49

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:36', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b2d26f09-7167-4a9f-bcd7-b27d932e8523' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:49
	System	14 Aug 2020 22:15:49

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:38', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b2d26f09-7167-4a9f-bcd7-b27d932e8523' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:49
	System	14 Aug 2020 22:15:49

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:40', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b2d26f09-7167-4a9f-bcd7-b27d932e8523' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:49
	System	14 Aug 2020 22:15:49

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:44', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b2d26f09-7167-4a9f-bcd7-b27d932e8523' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 22:15:49
	System	14 Aug 2020 22:15:49

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T17:15:46', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b2d26f09-7167-4a9f-bcd7-b27d932e8523' User entered '14 Aug 2020 17:15'	(b) (4), (b) (6) System	14 Aug 2020 22:15:49
	System	14 Aug 2020 22:15:49

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 17:14'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 19:44'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:22', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b001261e-0292-4092-b2d3-68e0cca72c92' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:39
	System	15 Aug 2020 02:05:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:24', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b001261e-0292-4092-b2d3-68e0cca72c92' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:39
	System	15 Aug 2020 02:05:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:25', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b001261e-0292-4092-b2d3-68e0cca72c92' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:39
	System	15 Aug 2020 02:05:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:27', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b001261e-0292-4092-b2d3-68e0cca72c92' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:39
	System	15 Aug 2020 02:05:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:29', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b001261e-0292-4092-b2d3-68e0cca72c92' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:39
	System	15 Aug 2020 02:05:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:30', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b001261e-0292-4092-b2d3-68e0cca72c92' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 02:05:39
	System	15 Aug 2020 02:05:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:32', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b001261e-0292-4092-b2d3-68e0cca72c92'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Aug 2020 02:05:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-14T21:05:35', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'b001261e-0292-4092-b2d3-68e0cca72c92'	(b) (4), (b) (6)	
User entered '14 Aug 2020 21:05'	System	15 Aug 2020 02:05:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '14 Aug 2020 20:39'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 2'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:46', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '46ca114a-680f-46ec-9fe1-e44e2659f9d0' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:07
	System	15 Aug 2020 17:11:07

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:48', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '46ca114a-680f-46ec-9fe1-e44e2659f9d0' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:07
	System	15 Aug 2020 17:11:07

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:49', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '46ca114a-680f-46ec-9fe1-e44e2659f9d0' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:07
	System	15 Aug 2020 17:11:07

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:50', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '46ca114a-680f-46ec-9fe1-e44e2659f9d0' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:07
	System	15 Aug 2020 17:11:07

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:51', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '46ca114a-680f-46ec-9fe1-e44e2659f9d0' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:07
	System	15 Aug 2020 17:11:07

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:53', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '46ca114a-680f-46ec-9fe1-e44e2659f9d0' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:07
	System	15 Aug 2020 17:11:07

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:10:54', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '46ca114a-680f-46ec-9fe1-e44e2659f9d0' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 17:11:07
	System	15 Aug 2020 17:11:07

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-15T12:11:04', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '46ca114a-680f-46ec-9fe1-e44e2659f9d0' User entered '15 Aug 2020 12:11'	(b) (4), (b) (6) System	15 Aug 2020 17:11:07
	System	15 Aug 2020 17:11:07

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 3'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:33', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bd7b88ab-6806-4db9-91a5-f8d03612b966' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 18:49:45
	System	16 Aug 2020 18:49:45

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:34', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bd7b88ab-6806-4db9-91a5-f8d03612b966' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 18:49:45
	System	16 Aug 2020 18:49:45

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:35', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bd7b88ab-6806-4db9-91a5-f8d03612b966' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 18:49:45
	System	16 Aug 2020 18:49:45

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:37', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bd7b88ab-6806-4db9-91a5-f8d03612b966' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 18:49:45
	System	16 Aug 2020 18:49:45

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:38', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bd7b88ab-6806-4db9-91a5-f8d03612b966' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 18:49:45
	System	16 Aug 2020 18:49:45

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:39', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bd7b88ab-6806-4db9-91a5-f8d03612b966' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 18:49:45
	System	16 Aug 2020 18:49:45

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:41', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bd7b88ab-6806-4db9-91a5-f8d03612b966'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Aug 2020 18:49:45

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-16T13:49:42', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bd7b88ab-6806-4db9-91a5-f8d03612b966' User entered '16 Aug 2020 13:49'	(b) (4), (b) (6) System	16 Aug 2020 18:49:45
	System	16 Aug 2020 18:49:45

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 4'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:26', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '325a3370-8b84-4983-986d-3130c7a62fcb' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 15:31:39
	System	18 Aug 2020 15:31:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:28', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '325a3370-8b84-4983-986d-3130c7a62fcb' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 15:31:39
	System	18 Aug 2020 15:31:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:29', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '325a3370-8b84-4983-986d-3130c7a62fcb' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 15:31:39
	System	18 Aug 2020 15:31:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:30', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '325a3370-8b84-4983-986d-3130c7a62fcb' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 15:31:39
	System	18 Aug 2020 15:31:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:31', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '325a3370-8b84-4983-986d-3130c7a62fcb' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 15:31:39
	System	18 Aug 2020 15:31:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:33', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '325a3370-8b84-4983-986d-3130c7a62fcb' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 15:31:39
	System	18 Aug 2020 15:31:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:35', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '325a3370-8b84-4983-986d-3130c7a62fcb' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 15:31:39
	System	18 Aug 2020 15:31:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-17T12:11:38', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '325a3370-8b84-4983-986d-3130c7a62fcb' User entered '17 Aug 2020 12:11'	(b) (4), (b) (6) System	18 Aug 2020 15:31:39
	System	18 Aug 2020 15:31:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 5'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:38', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8a38220-5ac0-49e5-8b84-6533c12e3829' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:02:24
	System	18 Aug 2020 17:02:24

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:43', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8a38220-5ac0-49e5-8b84-6533c12e3829'	(b) (4), (b) (6)	
	System	18 Aug 2020 17:02:24
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:02:24

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:45', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8a38220-5ac0-49e5-8b84-6533c12e3829' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:02:24
	System	18 Aug 2020 17:02:24

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:47', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8a38220-5ac0-49e5-8b84-6533c12e3829' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:02:24
	System	18 Aug 2020 17:02:24

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:48', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8a38220-5ac0-49e5-8b84-6533c12e3829' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:02:24
	System	18 Aug 2020 17:02:24

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:49', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8a38220-5ac0-49e5-8b84-6533c12e3829' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:02:24
	System	18 Aug 2020 17:02:24

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:51', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8a38220-5ac0-49e5-8b84-6533c12e3829' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 17:02:24
	System	18 Aug 2020 17:02:24

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-18T12:01:53', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8a38220-5ac0-49e5-8b84-6533c12e3829' User entered '18 Aug 2020 12:01'	(b) (4), (b) (6) System	18 Aug 2020 17:02:24
	System	18 Aug 2020 17:02:24

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 6'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:47', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '938dad5b-a480-40f9-8d61-f17e98171372' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:06
	System	19 Aug 2020 17:08:06

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:49', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '938dad5b-a480-40f9-8d61-f17e98171372' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:06
	System	19 Aug 2020 17:08:06

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:50', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '938dad5b-a480-40f9-8d61-f17e98171372' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:06
	System	19 Aug 2020 17:08:06

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:52', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '938dad5b-a480-40f9-8d61-f17e98171372' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:06
	System	19 Aug 2020 17:08:06

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:54', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '938dad5b-a480-40f9-8d61-f17e98171372' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:06
	System	19 Aug 2020 17:08:06

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:55', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '938dad5b-a480-40f9-8d61-f17e98171372' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:06
	System	19 Aug 2020 17:08:06

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:07:59', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '938dad5b-a480-40f9-8d61-f17e98171372' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 17:08:06
	System	19 Aug 2020 17:08:06

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-19T12:08:01', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '938dad5b-a480-40f9-8d61-f17e98171372' User entered '19 Aug 2020 12:08'	(b) (4), (b) (6) System	19 Aug 2020 17:08:06
	System	19 Aug 2020 17:08:06

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 7'	System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:17', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '71dfad90-d454-49d3-98e1-54725aa53578' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:51
	System	20 Aug 2020 17:01:51

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:19', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '71dfad90-d454-49d3-98e1-54725aa53578' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:51
	System	20 Aug 2020 17:01:51

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:21', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '71dfad90-d454-49d3-98e1-54725aa53578' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:51
	System	20 Aug 2020 17:01:51

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:22', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '71dfad90-d454-49d3-98e1-54725aa53578' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:51
	System	20 Aug 2020 17:01:51

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:24', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '71dfad90-d454-49d3-98e1-54725aa53578' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:51
	System	20 Aug 2020 17:01:51

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:25', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '71dfad90-d454-49d3-98e1-54725aa53578' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:51
	System	20 Aug 2020 17:01:51

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:31', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '71dfad90-d454-49d3-98e1-54725aa53578' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 17:01:51
	System	20 Aug 2020 17:01:51

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D8651985-9D3F-4266-96CB-BBEA37FF006A)', Time: '2020-08-20T12:01:34', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '71dfad90-d454-49d3-98e1-54725aa53578' User entered '20 Aug 2020 12:01'	(b) (4), (b) (6) System	20 Aug 2020 17:01:51
	System	20 Aug 2020 17:01:51

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:52:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:58
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:11:41
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	21 Aug 2020 18:33:28
	(b) (4)	

US3042209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:58
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:11:41
User entered '21 Aug 2020'		
	Rylea Gulick (b) (4)	21 Aug 2020 18:33:28
	(b) (4)	

US3042209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:58
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:11:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Rylea Gulick (b) (4)	21 Aug 2020 18:33:28
	(b) (4)	

US3042209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:58
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:11:41
User entered empty.		
	Rylea Gulick (b) (4)	21 Aug 2020 18:33:28
	(b) (4)	

US3042209

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:58
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:11:51
User entered 'Yes (Y)'	(b) (4)	
	Rylea Gulick (b) (4)	21 Aug 2020 18:33:31
	(b) (4)	

US3042209

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:58
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 18:33:31

US3042209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:12:12
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	01 Sep 2020 13:40:42
	(b) (4)	

US3042209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:12:12
User entered '28 Aug 2020'	Rylea Gulick (b) (4)	01 Sep 2020 13:40:42
	(b) (4)	

US3042209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:12:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 13:40:42

US3042209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:12:12
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 13:40:42

US3042209

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:12:20
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	01 Sep 2020 13:40:44
	(b) (4)	

US3042209

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User entered 'I'	(b) (4), (b) (6) System	01 Sep 2020 13:40:44

US3042209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:52:42
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:30:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:01
	(b) (4), (b) (6)	
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:22:40
	(b) (4)	

US3042209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:52:42
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:30:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:01
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:22:40
	(b) (4)	

US3042209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:52:42
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:30:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:01
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:22:40
	(b) (4)	

US3042209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:52:42
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:30:33
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:22:40

US3042209

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:52:52
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:30:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Oct 2020 21:22:43
	(b) (4)	

US3042209

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:11
User entered 'I'	(b) (4), (b) (6) System	20 Oct 2020 21:22:43

US3042209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:53:06
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:31:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:25
	(b) (4), (b) (6)	
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:23:21
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:53:06
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:31:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:25
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:23:21
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:53:06
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:31:29
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:25
User closed query 'Visit was not performed, however, System Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System).		20 Oct 2020 21:23:25
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:23:25
User opened query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System).	System	20 Oct 2020 21:23:21
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:23:21

US3042209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered 'VISIT2'	(b) (4), (b) (6) System	20 Oct 2020 21:23:21

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:39
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:09
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:09

US3042209

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:47
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:13
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:47
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:13
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:57
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:16
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:57
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:16
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:57
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:16
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:57
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:16
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:57
	(b) (4), (b) (6)	
User closed query 'Per CDM; Please record 'Was FSH sample collected?' as Yes or No. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 19:16:01
Query 'Per CDM; Please record 'Was FSH sample collected?' as Yes or No. Thank you.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4)	04 Dec 2020 22:21:58
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	04 Dec 2020 22:21:54
	(b) (4)	
User opened query 'Per CDM; Please record 'Was FSH sample collected?' as Yes or No. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:15:24
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:16
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:57
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:16
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:16:57
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:16
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:16

US3042209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:12
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:37
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:12
User entered 'Confirmed COVID-19 (COVID)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:37
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:12
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:37
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:37

US3042209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:12
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:37
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:12
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:37
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:37

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:12
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:37
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:12
User entered empty.	System	20 Oct 2020 21:24:37

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:37

US3042209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:23
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:41
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:23
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:41
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:23
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:41
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:41

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:31
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:45
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:45
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:31
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:45
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:31
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:45
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:45

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:24:45

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:31
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:45
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:31
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:24:45
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:24:45

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Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:44
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Oct 2020 21:24:48
	(b) (4)	

US3042209

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:27
User entered '1'	(b) (4), (b) (6) System	20 Oct 2020 21:24:48

US3042209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:43
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:54:42
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:10:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:58
	(b) (4), (b) (6)	
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:25:10
	(b) (4)	

US3042209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:43
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:54:42
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:10:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:58
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:25:10
	(b) (4)	

US3042209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:43
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:54:42
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:10:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:58
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:25:10
	(b) (4)	

US3042209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:42
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:10:52
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:17:58
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:10

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Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:43
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:54:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:11:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Oct 2020 21:25:13
	(b) (4)	

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Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:43
User entered '1'	(b) (4), (b) (6) System	20 Oct 2020 21:25:13

US3042209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:07
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:16
	(b) (4), (b) (6)	
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Oct 2020 21:25:18
	(b) (4)	

US3042209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:07
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:16
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:25:18
	(b) (4)	

US3042209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:07
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:16
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:25:18
	(b) (4)	

US3042209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:07
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:16
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:25:18
	(b) (4)	

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Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:19
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:37
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:25
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Oct 2020 21:25:21
	(b) (4)	

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Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:19
User entered 'I'	(b) (4), (b) (6) System	20 Oct 2020 21:25:21

US3042209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:27
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:36
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:51
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:36
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:26

US3042209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:27
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:36
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:51
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:26

US3042209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:27
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:36
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:51
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:26

US3042209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:56:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:36
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:51
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:36
	(b) (4), (b) (6)	
User entered empty.	Rylea Gulick (b) (4)	20 Oct 2020 21:25:26
	(b) (4)	

US3042209

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:27
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:55:47
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:18:44
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:29

US3042209

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:56:27
	(b) (4), (b) (6)	
User entered 'I'	System	20 Oct 2020 21:25:29

US3042209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:18:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:35

US3042209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:18:55
User entered '20 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:35

US3042209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[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 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:18:55
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:35

US3042209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User entered 'VISIT3'	(b) (4), (b) (6) System	20 Oct 2020 21:25:35

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered '20 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered '15:38'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User entered '20 Oct 2020 15:38'	(b) (4), (b) (6) System	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered '37.1' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered '90'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User entered 'bpm'	(b) (4), (b) (6) System	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered '119'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User entered 'mmHg'	(b) (4), (b) (6) System	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:02
User entered '80'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User entered 'mmHg'	(b) (4), (b) (6) System	20 Oct 2020 21:25:54

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 04:16:39

US3042209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 04:16:39

US3042209

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:15
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:59

US3042209

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:15
User entered '20 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:25:59

US3042209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:23
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:26:11

US3042209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:23
User entered '20 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:26:11

US3042209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:23
User entered '15:50'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:26:11

US3042209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User entered '20 Oct 2020 15:50'	(b) (4), (b) (6) System	20 Oct 2020 21:26:11

US3042209

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:19:31
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:26:12

US3042209

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:16:39
User entered '1'	(b) (4), (b) (6) System	20 Oct 2020 21:26:12

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 64'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-16T14:11:34', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9cf49c92-7d3c-4dce-9d46-ae276f299db7'	(b) (4), (b) (6)	
	System	16 Oct 2020 19:11:54
User entered 'No (N)'	System	16 Oct 2020 19:11:54

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-16T14:11:45', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9cf49c92-7d3c-4dce-9d46-ae276f299db7'	(b) (4), (b) (6)	
	System	16 Oct 2020 19:11:54
User entered 'No (N)'	System	16 Oct 2020 19:11:54

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-16T14:11:49', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9cf49c92-7d3c-4dce-9d46-ae276f299db7' User entered '16 Oct 2020 14:11:49'	(b) (4), (b) (6) System	16 Oct 2020 19:11:54
	System	16 Oct 2020 19:11:54

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 71'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-21T00:47:23', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '20c8c36f-4e99-4bae-a0ac-2ff0f14e875a'	(b) (4), (b) (6)	21 Oct 2020 05:47:31
User entered 'No (N)'	System	21 Oct 2020 05:47:31

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-21T00:47:25', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '20c8c36f-4e99-4bae-a0ac-2ff0f14e875a'	(b) (4), (b) (6)	21 Oct 2020 05:47:31
User entered 'No (N)'	System	21 Oct 2020 05:47:31

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-21T00:47:27', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '20c8c36f-4e99-4bae-a0ac-2ff0f14e875a' User entered '21 Oct 2020 00:47:27'	(b) (4), (b) (6) System	21 Oct 2020 05:47:31
	System	21 Oct 2020 05:47:31

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 78'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-28T01:51:40', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '53ba4ba3-9110-465c-aa12-c7c387536a07'	(b) (4), (b) (6)	28 Oct 2020 06:51:53
User entered 'No (N)'	System	28 Oct 2020 06:51:53

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-28T01:51:48', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '53ba4ba3-9110-465c-aa12-c7c387536a07'	(b) (4), (b) (6)	28 Oct 2020 06:51:53
User entered 'No (N)'	System	28 Oct 2020 06:51:53

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-10-28T01:51:51', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '53ba4ba3-9110-465c-aa12-c7c387536a07' User entered '28 Oct 2020 01:51:51'	(b) (4), (b) (6) System	28 Oct 2020 06:51:53
	System	28 Oct 2020 06:51:53

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 92'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-11-11T03:35:30', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '1324d953-db44-4390-bfa6-1072c0cbe288'	(b) (4), (b) (6)	11 Nov 2020 09:35:58
User entered 'No (N)'	System	11 Nov 2020 09:35:58

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-11-11T03:35:41', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '1324d953-db44-4390-bfa6-1072c0cbe288'	(b) (4), (b) (6)	11 Nov 2020 09:35:58
User entered 'Yes (Y)'	System	11 Nov 2020 09:35:58

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-11-11T03:35:45', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '1324d953-db44-4390-bfa6-1072c0cbe288'	(b) (4), (b) (6)	11 Nov 2020 09:35:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 09:35:58

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-11-11T03:35:49', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '1324d953-db44-4390-bfa6-1072c0cbe288' User entered '11 Nov 2020 03:35:49'	(b) (4), (b) (6) System	11 Nov 2020 09:35:58
	System	11 Nov 2020 09:35:58

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered 'Day 99'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-11-18T06:00:45', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '5f7c9955-ec1f-4866-8603-6f885173c556'	(b) (4), (b) (6)	
	System	18 Nov 2020 12:00:52
User entered 'No (N)'	System	18 Nov 2020 12:00:52

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-11-18T06:00:47', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '5f7c9955-ec1f-4866-8603-6f885173c556'	(b) (4), (b) (6)	
	System	18 Nov 2020 12:00:52
User entered 'No (N)'	System	18 Nov 2020 12:00:52

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-11-18T06:00:49', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '5f7c9955-ec1f-4866-8603-6f885173c556'	(b) (4), (b) (6)	
	System	18 Nov 2020 12:00:52
User entered '18 Nov 2020 06:00:49'	System	18 Nov 2020 12:00:52

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 21:58:39

US3042209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:26
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 21:58:39
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 21:58:39

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-02T03:09:13', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '3ac147b8-a8ac-41e7-b946-3155b899e4c1' User entered 'No (N)'	System	02 Dec 2020 09:09:28
	System	02 Dec 2020 09:09:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-02T03:09:22', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '3ac147b8-a8ac-41e7-b946-3155b899e4c1' User entered 'No (N)'	System	02 Dec 2020 09:09:28
	System	02 Dec 2020 09:09:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-02T03:09:25', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '3ac147b8-a8ac-41e7-b946-3155b899e4c1' User entered '02 Dec 2020 03:09:25'	System	02 Dec 2020 09:09:28
	System	02 Dec 2020 09:09:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-06T08:19:06', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'ae11c177-70c1-4e06-9864-d26aa3f11669' User entered 'No (N)'	System	06 Dec 2020 14:19:12
	System	06 Dec 2020 14:19:12

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-06T08:19:08', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'ae11c177-70c1-4e06-9864-d26aa3f11669' User entered 'No (N)'	System	06 Dec 2020 14:19:12
	System	06 Dec 2020 14:19:12

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-06T08:19:10', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'ae11c177-70c1-4e06-9864-d26aa3f11669' User entered '06 Dec 2020 08:19:10'	System	06 Dec 2020 14:19:12
	System	06 Dec 2020 14:19:12

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-13T00:22:32', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9b4ba6de-4bbc-4d9d-9d89-126b7d3c8cdf' User entered 'No (N)'	System	13 Dec 2020 06:22:41
	System	13 Dec 2020 06:22:41

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-13T00:22:36', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9b4ba6de-4bbc-4d9d-9d89-126b7d3c8cdf' User entered 'No (N)'	System	13 Dec 2020 06:22:41
	System	13 Dec 2020 06:22:41

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-13T00:22:39', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9b4ba6de-4bbc-4d9d-9d89-126b7d3c8cdf' User entered '13 Dec 2020 00:22:39'	System	13 Dec 2020 06:22:41
	System	13 Dec 2020 06:22:41

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-20T00:02:33', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'd3997d37-c104-4d3f-9ae3-f26b292d38b0'	System	20 Dec 2020 06:02:50
User entered 'No (N)'	System	20 Dec 2020 06:02:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-20T00:02:36', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'd3997d37-c104-4d3f-9ae3-f26b292d38b0'	System	20 Dec 2020 06:02:50
User entered 'No (N)'	System	20 Dec 2020 06:02:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-20T00:02:39', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'd3997d37-c104-4d3f-9ae3-f26b292d38b0' User entered '20 Dec 2020 00:02:39'	System	20 Dec 2020 06:02:50
	System	20 Dec 2020 06:02:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-27T05:53:16', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '30e43ed6-cfec-4d0f-ad0c-618e99aa21dd' User entered 'No (N)'	System	27 Dec 2020 11:53:23

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-27T05:53:19', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '30e43ed6-cfec-4d0f-ad0c-618e99aa21dd' User entered 'No (N)'	System	27 Dec 2020 11:53:23
	System	27 Dec 2020 11:53:23

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2020-12-27T05:53:22', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '30e43ed6-cfec-4d0f-ad0c-618e99aa21dd' User entered '27 Dec 2020 05:53:22'	System	27 Dec 2020 11:53:23
	System	27 Dec 2020 11:53:23

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-03T00:39:26', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '781abbfc-e2d0-4965-b877-ee1b448362f4' User entered 'No (N)'	System	03 Jan 2021 06:39:37
	System	03 Jan 2021 06:39:37

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-03T00:39:31', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '781abbfc-e2d0-4965-b877-ee1b448362f4' User entered 'No (N)'	System	03 Jan 2021 06:39:37
	System	03 Jan 2021 06:39:37

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-03T00:39:34', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '781abbfc-e2d0-4965-b877-ee1b448362f4' User entered '03 Jan 2021 00:39:34'	System	03 Jan 2021 06:39:37
	System	03 Jan 2021 06:39:37

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-10T00:34:28', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '8f1f30fe-4d18-45a4-a3fe-4ee4d3c45f02'	System	10 Jan 2021 06:34:36
User entered 'No (N)'	System	10 Jan 2021 06:34:36

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-10T00:34:30', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '8f1f30fe-4d18-45a4-a3fe-4ee4d3c45f02'	System	10 Jan 2021 06:34:36
User entered 'No (N)'	System	10 Jan 2021 06:34:36

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-10T00:34:34', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '8f1f30fe-4d18-45a4-a3fe-4ee4d3c45f02'	System	10 Jan 2021 06:34:36
User entered '10 Jan 2021 00:34:34'	System	10 Jan 2021 06:34:36

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-19T12:15:04', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '270863a6-df95-49ed-b1ee-f1ef294adc4a' User entered 'No (N)'	System	19 Jan 2021 18:15:11

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-19T12:15:07', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '270863a6-df95-49ed-b1ee-f1ef294adc4a' User entered 'No (N)'	System	19 Jan 2021 18:15:11

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-19T12:15:09', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '270863a6-df95-49ed-b1ee-f1ef294adc4a' User entered '19 Jan 2021 12:15:09'	System	19 Jan 2021 18:15:11
	System	19 Jan 2021 18:15:11

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-26T12:46:03', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'd54918ea-e7e8-4bc9-945d-fde549fd075a' User entered 'No (N)'	System	26 Jan 2021 19:50:34
	System	26 Jan 2021 19:50:34

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-26T12:46:05', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'd54918ea-e7e8-4bc9-945d-fde549fd075a' User entered 'No (N)'	System	26 Jan 2021 19:50:34
	System	26 Jan 2021 19:50:34

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-26T12:46:06', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'd54918ea-e7e8-4bc9-945d-fde549fd075a' User entered '26 Jan 2021 12:46:06'	System	26 Jan 2021 19:50:34

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-31T06:59:16', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '07e5850f-d6e3-4e7d-8b09-211c94cc9576' User entered 'No (N)'	System	31 Jan 2021 12:59:24
	System	31 Jan 2021 12:59:24

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-31T06:59:18', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '07e5850f-d6e3-4e7d-8b09-211c94cc9576' User entered 'No (N)'	System	31 Jan 2021 12:59:24
	System	31 Jan 2021 12:59:24

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D77DBF6D-CA4B-4DB9-8E47-E38BC385EFA9)', Time: '2021-01-31T06:59:20', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '07e5850f-d6e3-4e7d-8b09-211c94cc9576' User entered '31 Jan 2021 06:59:20'	System	31 Jan 2021 12:59:24
	System	31 Jan 2021 12:59:24

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-02-07T19:49:12', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4b829af9-3259-4e62-8ac7-e7b7fb8615fe'	System	08 Feb 2021 01:49:19
User entered 'No (N)'	System	08 Feb 2021 01:49:19

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-02-07T19:49:14', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4b829af9-3259-4e62-8ac7-e7b7fb8615fe'	System	08 Feb 2021 01:49:19
User entered 'No (N)'	System	08 Feb 2021 01:49:19

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-02-07T19:49:17', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4b829af9-3259-4e62-8ac7-e7b7fb8615fe'	System	08 Feb 2021 01:49:19
User entered '07 Feb 2021 19:49:17'	System	08 Feb 2021 01:49:19

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-02-14T17:52:21', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9781ca6f-0fce-438a-a97c-b60d703752b8'	System	14 Feb 2021 23:52:28
User entered 'No (N)'	System	14 Feb 2021 23:52:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-02-14T17:52:24', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9781ca6f-0fce-438a-a97c-b60d703752b8'	System	14 Feb 2021 23:52:28
User entered 'No (N)'	System	14 Feb 2021 23:52:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-02-14T17:52:26', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '9781ca6f-0fce-438a-a97c-b60d703752b8'	System	14 Feb 2021 23:52:28
User entered '14 Feb 2021 17:52:26'	System	14 Feb 2021 23:52:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-02-23T10:18:34', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bb824d84-869d-4b5d-8832-72f88e1c661b'	System	23 Feb 2021 16:18:44
User entered 'No (N)'	System	23 Feb 2021 16:18:44

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-02-23T10:18:36', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bb824d84-869d-4b5d-8832-72f88e1c661b'	System	23 Feb 2021 16:18:44
User entered 'No (N)'	System	23 Feb 2021 16:18:44

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-02-23T10:18:41', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'bb824d84-869d-4b5d-8832-72f88e1c661b'	System	23 Feb 2021 16:18:44
User entered '23 Feb 2021 10:18:41'	System	23 Feb 2021 16:18:44

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-03-01T14:12:04-06:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '2e64a0b9-a9fb-44a4-b972-d3d22018fb7d'	System	01 Mar 2021 20:12:10
User entered 'No (N)'	System	01 Mar 2021 20:12:10

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-03-01T14:12:06-06:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '2e64a0b9-a9fb-44a4-b972-d3d22018fb7d'	System	01 Mar 2021 20:12:10
User entered 'No (N)'	System	01 Mar 2021 20:12:10

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-03-01T14:12:08-06:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '2e64a0b9-a9fb-44a4-b972-d3d22018fb7d'	System	01 Mar 2021 20:12:10
User entered '01 Mar 2021 14:12:08'	System	01 Mar 2021 20:12:10

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-03-07T07:18:54-06:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '073990bd-ad20-4696-8b06-3e9a3b212528'	System	07 Mar 2021 13:19:05
User entered 'No (N)'	System	07 Mar 2021 13:19:05

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-03-07T07:18:58-06:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '073990bd-ad20-4696-8b06-3e9a3b212528'	System	07 Mar 2021 13:19:05
User entered 'No (N)'	System	07 Mar 2021 13:19:05

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-03-07T07:19:00-06:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '073990bd-ad20-4696-8b06-3e9a3b212528'	System	07 Mar 2021 13:19:05
User entered '07 Mar 2021 07:19:00'	System	07 Mar 2021 13:19:05

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-03-14T23:30:38-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '6d93ed0d-d6e3-4d56-9e9c-2e7b3a91b5aa'	System	15 Mar 2021 04:30:48
User entered 'No (N)'	System	15 Mar 2021 04:30:48

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-03-14T23:30:41-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '6d93ed0d-d6e3-4d56-9e9c-2e7b3a91b5aa'	System	15 Mar 2021 04:30:48
User entered 'No (N)'	System	15 Mar 2021 04:30:48

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-03-14T23:30:43-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '6d93ed0d-d6e3-4d56-9e9c-2e7b3a91b5aa' User entered '14 Mar 2021 23:30:43'	System	15 Mar 2021 04:30:48
	System	15 Mar 2021 04:30:48

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-03-21T06:54:41-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'df8b3b47-6404-4d82-80b2-01730c816f11'	System	21 Mar 2021 11:55:06
User entered 'No (N)'	System	21 Mar 2021 11:55:06

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-03-21T06:54:44-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'df8b3b47-6404-4d82-80b2-01730c816f11'	System	21 Mar 2021 11:55:06
User entered 'No (N)'	System	21 Mar 2021 11:55:06

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-03-21T06:54:49-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'df8b3b47-6404-4d82-80b2-01730c816f11'	System	21 Mar 2021 11:55:06
User entered '21 Mar 2021 06:54:49'	System	21 Mar 2021 11:55:06

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-03-29T01:58:17-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '8c3af4ef-3008-402e-93e6-733d68c3daf5'	System	29 Mar 2021 06:58:26
User entered 'No (N)'	System	29 Mar 2021 06:58:26

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-03-29T01:58:20-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '8c3af4ef-3008-402e-93e6-733d68c3daf5'	System	29 Mar 2021 06:58:26
User entered 'No (N)'	System	29 Mar 2021 06:58:26

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-03-29T01:58:21-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '8c3af4ef-3008-402e-93e6-733d68c3daf5'	System	29 Mar 2021 06:58:26
User entered '29 Mar 2021 01:58:21'	System	29 Mar 2021 06:58:26

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-04-04T03:18:39-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4198fb5f-9a7a-4dc9-8288-781a4ce70b34'	System	04 Apr 2021 08:18:49
User entered 'No (N)'	System	04 Apr 2021 08:18:49

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-04-04T03:18:42-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4198fb5f-9a7a-4dc9-8288-781a4ce70b34'	System	04 Apr 2021 08:18:49
User entered 'No (N)'	System	04 Apr 2021 08:18:49

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-04-04T03:18:45-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '4198fb5f-9a7a-4dc9-8288-781a4ce70b34'	System	04 Apr 2021 08:18:49
User entered '04 Apr 2021 03:18:45'	System	04 Apr 2021 08:18:49

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-04-12T12:35:13-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '48946507-8dff-4c56-9b89-1ccebd91998a' User entered 'No (N)'	System	12 Apr 2021 17:35:28
	System	12 Apr 2021 17:35:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-04-12T12:35:16-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '48946507-8dff-4c56-9b89-1ccebd91998a'	System	12 Apr 2021 17:35:28
User entered 'No (N)'	System	12 Apr 2021 17:35:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-04-12T12:35:18-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '48946507-8dff-4c56-9b89-1ccebd91998a'	System	12 Apr 2021 17:35:28
User entered '12 Apr 2021 12:35:18'	System	12 Apr 2021 17:35:28

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-04-21T11:19:52-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'a9ba1678-9d5a-40b2-90b6-e88281b86538'	System	21 Apr 2021 16:20:02
User entered 'No (N)'	System	21 Apr 2021 16:20:02

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-04-21T11:19:54-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'a9ba1678-9d5a-40b2-90b6-e88281b86538'	System	21 Apr 2021 16:20:02
User entered 'No (N)'	System	21 Apr 2021 16:20:02

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-04-21T11:19:56-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'a9ba1678-9d5a-40b2-90b6-e88281b86538'	System	21 Apr 2021 16:20:02
User entered '21 Apr 2021 11:19:56'	System	21 Apr 2021 16:20:02

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-04-27T08:27:41-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '691024c8-fe2f-4167-b3a2-12d4d3d79a8a' User entered 'No (N)'	System	29 Apr 2021 00:58:05
	System	29 Apr 2021 00:58:05

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-04-27T08:27:43-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '691024c8-fe2f-4167-b3a2-12d4d3d79a8a'	System	29 Apr 2021 00:58:05
User entered 'No (N)'	System	29 Apr 2021 00:58:05

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-04-27T08:27:45-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '691024c8-fe2f-4167-b3a2-12d4d3d79a8a'	System	29 Apr 2021 00:58:05
User entered '27 Apr 2021 08:27:45'	System	29 Apr 2021 00:58:05

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[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 (c9b89c5cb597acc3)', Time: '2021-05-03T08:09:49-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8bbce16-18da-4abc-a308-6b4378218c33'	System	03 May 2021 13:09:56
User entered 'No (N)'	System	03 May 2021 13:09:56

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Have you been exposed to someone with 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 (c9b89c5cb597acc3)', Time: '2021-05-03T08:09:51-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8bbce16-18da-4abc-a308-6b4378218c33'	System	03 May 2021 13:09:56
User entered 'No (N)'	System	03 May 2021 13:09:56

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-05-03T08:09:52-05:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: 'e8bbce16-18da-4abc-a308-6b4378218c33'	System	03 May 2021 13:09:56
User entered '03 May 2021 08:09:52'	System	03 May 2021 13:09:56

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 08:08:50

US3042209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:08:50
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 08:08:50

US3042209

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:52:12

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)	24 Apr 2021 12:43:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-03-01T14:12:13-06:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '8ded9a48-72f4-44f1-9562-33c6fe796585'	(b) (4), (b) (6)	01 Mar 2021 20:12:19
User entered 'No (N)'	System	01 Mar 2021 20:12:19

US3042209

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:52:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:43:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9b89c5cb597acc3)', Time: '2021-03-01T14:12:15-06:00', User OID: 'PatientReportedOutcome (US3042209)', ODM File OID: '8ded9a48-72f4-44f1-9562-33c6fe796585'	(b) (4), (b) (6)	01 Mar 2021 20:12:19
User entered '01 Mar 2021 14:12:15'	System	01 Mar 2021 20:12:19

US3042209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:35:02

US3042209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:01
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:35:02

US3042209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Nov 2020 18:35:02

US3042209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:35:02

US3042209

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:35:14

US3042209

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:29
User entered 'I'	(b) (4), (b) (6) System	12 Nov 2020 18:35:14

US3042209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:00:02
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:23:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:20:21
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 20:35:19

US3042209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:00:02
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:23:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:20:21
	(b) (4), (b) (6)	
User entered '08 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 20:35:19

US3042209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:00:02
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:23:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:20:21
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Dec 2020 20:35:19

US3042209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:23:31
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:20:21
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 20:35:19

US3042209

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:00:12
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:23:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:20:28
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 17:31:37

US3042209

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User entered '1'	(b) (4), (b) (6) System	21 Dec 2020 17:31:37

US3042209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:27:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 17:02:41

US3042209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:27:56
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 17:02:41

US3042209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:27:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 17:02:41

US3042209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:27:56
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 17:02:41

US3042209

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:28:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 17:02:29

US3042209

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User entered '1'	(b) (4), (b) (6) System	06 Jan 2021 17:02:29

US3042209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:00:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	26 Feb 2021 22:59:33
	(b) (4)	

US3042209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:00:37
User entered '05 Feb 2021'	Rylea Gulick (b) (4)	26 Feb 2021 22:59:33
	(b) (4)	

US3042209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:00:37
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	26 Feb 2021 22:59:33
	(b) (4)	

US3042209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:00:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 22:59:33

US3042209

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:00:50
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	26 Feb 2021 22:59:35
	(b) (4)	

US3042209

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User entered '1'	(b) (4), (b) (6) System	26 Feb 2021 22:59:35

US3042209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	26 Feb 2021 22:59:44
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:01:04
User entered '26 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 22:59:44

US3042209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:04
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	26 Feb 2021 22:59:44
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'VISIT4'	(b) (4), (b) (6) System	26 Feb 2021 22:59:44

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered 'No (N)'		
	Jamie Thompson (b) (4)	30 Mar 2021 17:47:03
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.		
	Jamie Thompson (b) (4)	30 Mar 2021 17:47:03
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.		
	Jamie Thompson (b) (4)	30 Mar 2021 17:47:03
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:47:03

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.	Jamie Thompson (b) (4)	30 Mar 2021 17:47:03
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.		
	Jamie Thompson (b) (4)	30 Mar 2021 17:47:03
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.	Jamie Thompson (b) (4)	30 Mar 2021 17:47:03
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.	Jamie Thompson (b) (4)	30 Mar 2021 17:47:03
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:47:03

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:47:03

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:47:03

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.		
	Jamie Thompson (b) (4)	30 Mar 2021 17:47:03
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:47:03

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:01:15
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:47:03

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:47:03

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 13:14:25

US3042209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 13:14:25

US3042209

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:27
User entered 'No (N)'		
	Rylea Gulick (b) (4)	26 Feb 2021 22:59:46
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:27
User entered empty.		
	Rylea Gulick (b) (4)	26 Feb 2021 22:59:46
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:37
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:59:09
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:37
User entered '26 Feb 2021'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:59:09
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:01:37
User entered '13:57'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:59:09
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '26 Feb 2021 13:57'	(b) (4), (b) (6) System	12 Mar 2021 15:59:09

US3042209

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:46
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	26 Feb 2021 22:59:51
	(b) (4)	

US3042209

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '1'	(b) (4), (b) (6) System	26 Feb 2021 22:59:51

US3042209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:43:38

US3042209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:43:38

US3042209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:43:38

US3042209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:43:38

US3042209

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:43:50

US3042209

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 15:43:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:12

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:46
User entered '08 Sep 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	04 Nov 2020 21:19:47
User entered '03 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:19

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:12

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:46
User entered '00:00'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:19

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:12

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '08 Sep 2020 00:00'	(b) (4), (b) (6)	
	System	04 Nov 2020 21:19:47
User entered '03 Sep 2020 00:00'	System	29 Sep 2020 20:42:19

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:12

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:46
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:19

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:12

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:20:46
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:19

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 1 (Day 1)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User closed query 'Per CDM Re-Query: response is noted however please confirm that 08SEP2020 is the initial start date of symptoms as both Day 1 and Contact Date are recorded as 08SEP2020 or make appropriate updates.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:04:33
Query 'Per CDM Re-Query: response is noted however please confirm that 08SEP2020 is the initial start date of symptoms as both Day 1 and Contact Date are recorded as 08SEP2020 or make appropriate updates.' answered with 'SUBJECT IS UNSURE OF WHEN THEIR SYMPTOMS STARTED.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 18:05:35
User opened query 'Per CDM Re-Query: response is noted however please confirm that 08SEP2020 is the initial start date of symptoms as both Day 1 and Contact Date are recorded as 08SEP2020 or make appropriate updates.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 21:19:48
User closed query 'Per CDM; it appears Contact Date is 03SEP2020 and DAY1 is 08SEP2020. Please confirm that 08SEP2020 is the actual date of initial symptoms or update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 21:19:48
Query 'Per CDM; it appears Contact Date is 03SEP2020 and DAY1 is 08SEP2020. Please confirm that 08SEP2020 is the actual date of initial symptoms or update accordingly.' answered with 'Patient seen in clinic 08SEP2020; contact date updated to reflect clinical data' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	04 Nov 2020 21:20:20
User opened query 'Per CDM; it appears Contact Date is 03SEP2020 and DAY1 is 08SEP2020. Please confirm that 08SEP2020 is the actual date of initial symptoms or update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 09:21:21
User entered '08 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '36.9' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:47:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 2 (Day 2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '09 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:49:32

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 3 (Day 3)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '10 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:50:27

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 4 (Day 4)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '11 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:51:23

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 5 (Day 5)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '12 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:52:39

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 6 (Day 6)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '13 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.1' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:53:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 7 (Day 7)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '14 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:54:22

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 8 (Day 8)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '15 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.1' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:55:16

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 9 (Day 9)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.1' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:03

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 10 (Day 10)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '17 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.1' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:56:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 11 (Day 11)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '18 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:57:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 12 (Day 12)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '19 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:58:37

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:58:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 13 (Day 13)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '20 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '99'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:59:37

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 14 (Day 14)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '21 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 15 (Day 15)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '22 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '99'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:01:49

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 16 (Day 16)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '23 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.1' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:02:51

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 17 (Day 17)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '24 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:05:55

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 18 (Day 18)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '25 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:06:42

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.7' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:06:42

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 19 (Day 19)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '26 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.4' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:07:28

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 20 (Day 20)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '27 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:08:21

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 21 (Day 21)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '28 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:09

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 22 (Day 22)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '29 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:09:50

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 23 (Day 23)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '30 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:30:38

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 24 (Day 24)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '01 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '98.1' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:31:20

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 25 (Day 25)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '02 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:00

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 26 (Day 26)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '03 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:32:34

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User entered 'Day 27 (Day 27)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '04 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '0'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '%'	(b) (4), (b) (6) System	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:52:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:21:56
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:33:06

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:12

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
User entered '08 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:12

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:12

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
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)	01 Oct 2020 03:18:52
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 'ENTRY WILL BE ADDED' (Site from System).	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:46
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	29 Sep 2020 20:42:40
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:12

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
User entered '08 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:12

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:12

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

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[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)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:42:40

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User entered '1'	(b) (4), (b) (6) System	29 Sep 2020 20:42:40

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Generated On: 11 Aug 2021 21:52:12

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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Generated On: 11 Aug 2021 21:52:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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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)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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[Start Date](#)

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[End Date](#)

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
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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)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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[Start Date](#)

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[End Date](#)

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
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User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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[Mechanical Ventilation?](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
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User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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[ECMO?](#)

Audit	User	Time (GMT)
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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
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[Evidence of Shock Requires
Vasopressors](#)

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User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

US3042209

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 20:45:59

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:52:12

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:53:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:41:56
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:54:31
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:23:43
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	09 Sep 2020 12:36:48

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 3.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:32:41
Query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 3.' answered with 'DATE IS CORRECT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 14:55:38
User opened query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 3.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:13:21
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F638502098 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm "correct date" for Day 3 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:13:21
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F638502098 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm "correct date" for Day 3 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' answered with 'COLLECTION DATE CANNOT BE CHANGED IN PPD' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	23 Mar 2021 15:50:44
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F638502098 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm "correct date" for Day 3 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 17:35:45

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F638502098 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:13:55
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F638502098 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' answered with '14SEP2020 IS WHEN SAMPLE WAS RETURNED TO LAB' (Site from DM).	Rylea Gulick (b) (4)	02 Mar 2021 18:58:58
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F638502098 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:06:20
User accepted default value 'Day 3 (Day 3)'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:52:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered 'Yes (Y)'	Meagan Millert (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10,12,16,21,28SEP2020 is recorded under Illness Visit Day 3,5,9,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 05:16:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10,12,16,21,28SEP2020 is recorded under Illness Visit Day 3,5,9,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '07OCT2020 SHIPMENT TRACKING: 914897843125.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 16:31:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10,12,16,21,28SEP2020 is recorded under Illness Visit Day 3,5,9,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:50:50
User entered '10 Sep 2020'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 5.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:32:45
Query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 5.' answered with 'DATE IS CORRECT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 14:56:04
User opened query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 5.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:13:31
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : PPD reports Day 5 sample with Accession # 1F652651602 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day 5 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:13:31
Query 'Per GCL LAB reconciliation: Saliva Re-query : PPD reports Day 5 sample with Accession # 1F652651602 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day 5 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' answered with 'COLLECTION DATE CANNOT BE CHANGED IN PPD.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	23 Mar 2021 15:50:55
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : PPD reports Day 5 sample with Accession # 1F652651602 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day 5 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 17:36:41

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F652651602 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:14:27
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F652651602 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' answered with '14SEP2020 IS WHEN SAMPLE WAS RETURNED TO LAB' (Site from DM).	Rylea Gulick (b) (4)	02 Mar 2021 18:59:10
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F652651602 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:07:27
User accepted default value 'Day 5 (Day 5)'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:52:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered 'Yes (Y)'	Meagan Millert (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered '12 Sep 2020'	Meagan Millert (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F635878554 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:14:32
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F635878554 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' answered with '14SEP2020 IS WHEN SAMPLE WAS COLLECTED AND RETURNED TO LAB' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 18:59:27
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F635878554 is reported with 14SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:08:21
User accepted default value 'Day 7 (Day 7)'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:52:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered 'Yes (Y)'	Meagan Millert (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered '14 Sep 2020'	Meagan Millert (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:52:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered 'Yes (Y)'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
User closed query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 9.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:32:51
Query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 9.' answered with 'DATE IS CORRECT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 14:56:51
User opened query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 9.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:13:41
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : PPD reports Day 9 sample with Accession # 1F640514066 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:13:41
Query 'Per GCL LAB reconciliation: Saliva Re-query : PPD reports Day 9 sample with Accession # 1F640514066 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' answered with 'COLLECTION DATE CANNOT BE CHANGED IN PPD' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	23 Mar 2021 15:51:09
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : PPD reports Day 9 sample with Accession # 1F640514066 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 17:37:31

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F640514066 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:14:38
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F640514066 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' answered with '06OCT2020 IS WHEN SAMPLE WAS RETURNED TO LAB' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 18:59:38
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F640514066 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:09:09
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered '16 Sep 2020'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:52:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered 'Yes (Y)'	Meagan Millert (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User closed query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 14.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:32:55
Query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 14.' answered with 'DATE IS CORRECT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 14:57:21
User opened query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, however please confirm correct of date of collection for day 14.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:14:00
User closed query 'Per GCL LAB reconciliation: Saliva Re-query: PPD reports Day 14 sample with Accession # 1F650522128 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:14:00
Query 'Per GCL LAB reconciliation: Saliva Re-query: PPD reports Day 14 sample with Accession # 1F650522128 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' answered with 'COLLECTION DATE CANNOT BE CHANGED IN PPD' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	23 Mar 2021 15:51:18
User opened query 'Per GCL LAB reconciliation: Saliva Re-query: PPD reports Day 14 sample with Accession # 1F650522128 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 17:38:11

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F650522128 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:14:45
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F650522128 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' answered with '06OCT2020 IS WHEN SAMPLE WAS RETURNED TO LAB' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 18:59:50
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F650522128 is reported with 06OCT2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:09:55
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered '21 Sep 2020'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:47:57
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Patient did not collect day 21 sample' (Site from DM).	Jamie Thompson (b) (4)	04 Nov 2020 21:28:20
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:06:56
User accepted default value 'Day 21 (Day 21)'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:52:12

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:04:40
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 28SEP2020 for Day 21 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. If the Sample was not collected at Day 21 then please update the EDC accordingly . Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:14:53
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 28SEP2020 for Day 21 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. If the Sample was not collected at Day 21 then please update the EDC accordingly . Thank you.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 19:11:21
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 19:11:14
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 19:11:14
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 28SEP2020 for Day 21 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. If the Sample was not collected at Day 21 then please update the EDC accordingly . Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:12:57
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:27:44
User closed query 'Per CDM: response is recorded as NO but date of collection is present. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 04:56:16
Query 'Per CDM: response is recorded as NO but date of collection is present. Please reconcile.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 18:05:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 18:05:51
User opened query 'Per CDM: response is recorded as NO but date of collection is present. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 21:21:10

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:52:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	04 Nov 2020 21:28:04
User entered 'Yes (Y)'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:04:40
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 19:11:14
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered '28 Sep 2020'	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:52:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User closed query 'Per CDM Re-Query: previous query responses are noted; however, please confirm Saliva sample was not collected as expected or make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:05:51
Query 'Per CDM Re-Query: previous query responses are noted; however, please confirm Saliva sample was not collected as expected or make all applicable updates.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 18:06:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 18:06:34
User opened query 'Per CDM Re-Query: previous query responses are noted; however, please confirm Saliva sample was not collected as expected or make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 21:23:59
User closed query 'Please confirm if the Day 28 saliva sample was collected as expected.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 20:42:46
Query 'Please confirm if the Day 28 saliva sample was collected as expected.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	21 Oct 2020 21:47:26
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	21 Oct 2020 21:47:16
User opened query 'Please confirm if the Day 28 saliva sample was collected as expected.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:32:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 11:53:46
Query 'Data is required. Please complete.' answered with 'when visit occurs staff will enter it' (Site from System).	Meagan Miller (b) (4)	02 Oct 2020 19:50:03
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:47:28
User entered empty.	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:44
User entered '06 Oct 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 18:06:34
User entered empty.	Meagan Miller (b) (4)	02 Oct 2020 19:47:28

US3042209

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:06
User closed query 'Per ETRTR: Please complete Saliva Collection, Symptoms Log and other COVID 19 Assessments pages, thanks.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 20:50:36
Query 'Per ETRTR: Please complete Saliva Collection, Symptoms Log and other COVID 19 Assessments pages, thanks.' answered with 'staff enter the visits that occurred' (Site from CRA).	Meagan Miller (b) (4)	02 Oct 2020 19:51:39
User opened query 'Per ETRTR: Please complete Saliva Collection, Symptoms Log and other COVID 19 Assessments pages, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 23:01:23
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:16:08

US3042209

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:25:06
User entered '08 Sep 2020'	Rylea Gulick (b) (4)	09 Sep 2020 00:16:08
	(b) (4)	

US3042209

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:06
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:16:08

US3042209

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User entered 'SICKD1'	(b) (4), (b) (6) System	09 Sep 2020 00:16:08

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '08 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '17:14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User entered '08 Sep 2020 17:14'	(b) (4), (b) (6) System	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '163.83' cm	Rylea Gulick (b) (4)	09 Sep 2020 00:17:19
DataPoint set to visible.	(b) (4) System	09 Sep 2020 00:16:08

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '86.0' kg	Rylea Gulick (b) (4)	09 Sep 2020 00:17:19
DataPoint set to visible.	(b) (4) System	09 Sep 2020 00:16:08

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '36.9' C	Rylea Gulick (b) (4)	09 Sep 2020 00:17:19
	(b) (4)	

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '76'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User entered 'bpm'	(b) (4), (b) (6) System	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '14'	Rylea Gulick (b) (4)	09 Sep 2020 00:17:19
	(b) (4)	

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '122'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User entered 'mmHg'	(b) (4), (b) (6) System	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:25:26
User entered '86'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User entered 'mmHg'	(b) (4), (b) (6) System	09 Sep 2020 00:17:19

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:16:03

US3042209

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:16:03

US3042209

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:25:38
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	09 Sep 2020 00:17:54
	(b) (4)	

US3042209

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:25:38
User entered '08 Sep 2020'	Rylea Gulick (b) (4)	09 Sep 2020 00:17:54
	(b) (4)	

US3042209

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:52:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:59

US3042209

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:10
User entered '08 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 00:17:59

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:25
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:17

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:25
User entered '06 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:17

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:25
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:17

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User entered 'SICKD28'	(b) (4), (b) (6) System	16 Oct 2020 16:31:17

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '06 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '07:55'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User entered '06 Oct 2020 07:55'	(b) (4), (b) (6) System	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '163.83' cm	Rylea Gulick (b) (4)	16 Oct 2020 16:31:50
DataPoint set to visible.	(b) (4) System	16 Oct 2020 16:31:17

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '86.4' kg	Rylea Gulick (b) (4)	16 Oct 2020 16:31:50
DataPoint set to visible.	(b) (4) System	16 Oct 2020 16:31:17

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '36.8' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '77'	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User entered 'bpm'	(b) (4), (b) (6) System	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '12'	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '120'	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User entered 'mmHg'	(b) (4), (b) (6) System	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:26:36
User entered '83'	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User entered 'mmHg'	(b) (4), (b) (6) System	16 Oct 2020 16:31:50

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:28:22

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:28:22

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:27:10
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Oct 2020 16:31:54
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:27:10
User entered '06 Oct 2020'	Rylea Gulick (b) (4)	16 Oct 2020 16:31:54
	(b) (4)	

US3042209

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:52:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:25
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:58

US3042209

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:52:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:27:25
User entered '06 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:31:58

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	16 Oct 2020 16:31:17

US3042209

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	16 Oct 2020 16:31:17

US3042209

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

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:11
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:54:41
	(b) (4)	

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

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:11
User entered '11 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:54:41

US3042209

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

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:11
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:54:41

US3042209

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

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	12 Mar 2021 15:54:41

US3042209

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered '11 Mar 2021'	Rylea Gulick (b) (4)	12 Mar 2021 15:54:56
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:54:56

US3042209

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:54:56
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:54:56

US3042209

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered '11 Mar 2021'	Rylea Gulick (b) (4)	12 Mar 2021 15:54:56

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered 'Placebo (Placebo)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:54:56

US3042209

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered 'Placebo (Placebo)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:54:56

US3042209

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered 'Placebo (Placebo)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:54:56

US3042209

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:21
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:54:56

US3042209

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '1'	(b) (4), (b) (6) System	12 Mar 2021 15:54:56

US3042209

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'I'	(b) (4), (b) (6) System	12 Mar 2021 15:54:56

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered missing code ND - Not Done.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered missing code ND - Not Done.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6)	
	System	12 Mar 2021 15:57:30
DataPoint set to visible.	System	12 Mar 2021 15:54:56

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered missing code ND - Not Done.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered missing code ND - Not Done.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6)	
	System	12 Mar 2021 15:57:30
DataPoint set to visible.	System	12 Mar 2021 15:54:56

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30
	(b) (4)	

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '11 Mar 2021'	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '18:15'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30
	(b) (4)	

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '11 Mar 2021 18:15'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '36.9' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '79'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'bpm'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '126'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'mmHg'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'mmHg'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered missing code ND - Not Done.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered missing code ND - Not Done.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 15:57:30
DataPoint set to visible.	System	12 Mar 2021 15:54:56

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '11 Mar 2021'	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '19:38'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '11 Mar 2021 19:38'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '36.9' C		
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30
	(b) (4)	

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '76'	(b) (4)	
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'bpm'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '12'	(b) (4)	
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:30
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '120'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'mmHg'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:33
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:30

US3042209

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'mmHg'	(b) (4), (b) (6) System	12 Mar 2021 15:57:30

US3042209

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:45
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:34
	(b) (4)	

US3042209

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:45
User entered '11 Mar 2021'	Rylea Gulick (b) (4)	12 Mar 2021 15:57:34

US3042209

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:55
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:56:26
	(b) (4)	

US3042209

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:55
User entered '11 Mar 2021'	Rylea Gulick (b) (4)	12 Mar 2021 15:56:26

US3042209

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:55
User entered 'Urine (URINE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:56:26

US3042209

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:55
User entered 'Negative (NEGATIVE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:56:26

US3042209

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:05:55
User entered 'No (N)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:56:26
	(b) (4)	

US3042209

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:56:26

US3042209

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:05:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:56:26

US3042209

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 15:56:26

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:06:09
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:46
	(b) (4)	

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:06:09
User entered empty.		
	Rylea Gulick (b) (4)	12 Mar 2021 15:57:46
	(b) (4)	

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:06:09
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:46

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'mRNA-1273'	(b) (4), (b) (6)	
	System	12 Mar 2021 15:57:46
DataPoint set to visible.	System	12 Mar 2021 15:54:56

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:06:09
User entered '11 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:46

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:06:09
User entered '19:04'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:46

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '11 Mar 2021 19:04'	(b) (4), (b) (6) System	12 Mar 2021 15:57:46

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:06:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:57:46

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:06:09
User entered 'ONCE'	System	12 Mar 2021 15:57:46

US3042209

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	12 Mar 2021 15:57:46

US3042209

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:06:22
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:55:01

US3042209

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:06:22
User entered '11 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:55:01

US3042209

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 19:06:22
User entered '18:25'		
	Rylea Gulick (b) (4)	12 Mar 2021 15:55:01
	(b) (4)	

US3042209

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '11 Mar 2021 18:25'	(b) (4), (b) (6) System	12 Mar 2021 15:55:01

US3042209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:06:30
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:55:06

US3042209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 11-MAR-2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 05:33:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:24:07
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:22
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 11-MAR-2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '16MAR2021 SHIPMENT TRACKING: 953942752039' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 13:41:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 11-MAR-2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 04:04:29
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:06:30
User entered '11 Mar 2021'	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 15:55:06

US3042209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:06:30
User entered '18:37'	Rylea Gulick (b) (4)	12 Mar 2021 15:55:06

US3042209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '11 Mar 2021 18:37'	(b) (4), (b) (6) System	12 Mar 2021 15:55:06

US3042209

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

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:06:44
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Mar 2021 15:55:09
	(b) (4)	

US3042209

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

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:14:25
User entered '1'	(b) (4), (b) (6) System	12 Mar 2021 15:55:09

US3042209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:07:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	31 Mar 2021 18:30:13

US3042209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:07:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	31 Mar 2021 18:30:13

US3042209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:07:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	31 Mar 2021 18:30:13

US3042209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:07:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	31 Mar 2021 18:30:13

US3042209

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Un-verified.	(b) (4) Rylea Gulick (b) (4)	13 Apr 2021 13:32:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	13 Apr 2021 13:32:46
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:10
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	31 Mar 2021 18:30:19

US3042209

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 13:32:46
User entered empty.	System	31 Mar 2021 18:30:19

US3042209

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 13:32:46
User entered empty.	System	31 Mar 2021 18:30:19
DataPoint set to visible.	System	31 Mar 2021 18:30:19

US3042209

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:32:56

US3042209

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered '12 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:32:56

US3042209

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:32:56

US3042209

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	13 Apr 2021 13:32:56

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered '12 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered '16:21'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User entered '12 Apr 2021 16:21'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered '36.7' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered '95'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered '120'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered '12 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered '17:00'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User entered '12 Apr 2021 17:00'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered '37.3' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered '78'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:16:23
User entered '116'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:16:23
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 13:33:49

US3042209

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:01

US3042209

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered '12 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:01

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:07

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:15:42
User entered '12 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:07

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:15:42
User entered 'Urine (URINE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:07

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered 'Negative (NEGATIVE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:07

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:07

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:07

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:15:42
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:33:07

US3042209

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 13:33:07

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	13 Apr 2021 13:34:19
DataPoint set to visible.	System	13 Apr 2021 13:32:46

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered '12 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:15:42
User entered '16:30'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User entered '12 Apr 2021 16:30'	System	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Apr 2021 13:34:19

US3042209

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Apr 2021 13:34:23

US3042209

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 13:34:23

US3042209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:18:44

US3042209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 18:49:08
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:19:36
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Apr 2021 20:18:44
User entered '23 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 20:18:44

US3042209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:18:44

US3042209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:18:44

US3042209

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:20:02

US3042209

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 20:20:02

US3042209

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:52:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:07:58
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:19
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:14

US3042209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:55:58
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:00
User entered	System	16 Sep 2020 18:13:55
'USA-US052-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	16 Sep 2020 18:13:55

US3042209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:55:59
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'Per DM CLR: Please consider updating event term to COVID-19, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:48:14
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	16 Oct 2020 16:37:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	16 Oct 2020 16:37:49
Data point term sent to Coder	System	16 Oct 2020 16:28:43
Query 'Per DM CLR: Please consider updating event term to COVID-19, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4)	16 Oct 2020 16:28:08
Coding entries removed.	Rylea Gulick (b) (4)	16 Oct 2020 16:28:02
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4)	
	Rylea Gulick (b) (4)	16 Oct 2020 16:28:02
User opened query 'Per DM CLR: Please consider updating event term to COVID-19, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 13:57:13
Query 'Per DM CLR: Please review event and record "Symptomatic Covid-19' if subject shows symptoms per ecrf guidelines. Review and update term as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:56:57
User opened query 'Per DM CLR: Please review event and record "Symptomatic Covid-19' if subject shows symptoms per ecrf guidelines. Review and update term as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:50:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: SARS-CoV-2 test positive - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 07:30:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 07:30:33
Data point term sent to Coder	System	16 Sep 2020 14:07:46
User entered 'SARS-COV-2 positive'	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:04
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:10
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:07
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:08:46
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'will complete' (Site from Safety).	Jamie Thompson (b) (4) (b) (4)	28 Sep 2020 16:48:24
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:42:24
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:56:09
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'PV Query: The COVID-19 assessment symptom log day 1 is captured as 08 Sep 2020. Please confirm that symptoms began on 04 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:34:42
Query 'PV Query: The COVID-19 assessment symptom log day 1 is captured as 08 Sep 2020. Please confirm that symptoms began on 04 Sep 2020.' answered with 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4)	16 Oct 2020 16:29:40
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Oct 2020 16:29:10
	(b) (4)	
User opened query 'PV Query: The COVID-19 assessment symptom log day 1 is captured as 08 Sep 2020. Please confirm that symptoms began on 04 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 14:30:43
Query 'PV Query: The COVID-19 assessment symptom log day 1 is captured as 08 Sep 2020. Please confirm that symptoms began on 04 Sep 2020.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:26:02
User opened query 'PV Query: The COVID-19 assessment symptom log day 1 is captured as 08 Sep 2020. Please confirm that symptoms began on 04 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:58:21
User closed query 'PV Query: The event onset date was reported as 04-Sep-2020, however Covid test sample wasn't collected until 08-Sep-2020. Please clarify if the subject was experiencing symptom onset on 04-Sep-2020. If yes, please provide the symptoms. If no, please considering updating event onset date to date of first symptoms or date of sample collection (if subject remained asymptomatic).' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:58:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: The event onset date was reported as 04-Sep-2020, however Covid test sample wasn't collected until 08-Sep-2020. Please clarify if the subject was experiencing symptom onset on 04-Sep-2020. If yes, please provide the symptoms. If no, please considering updating event onset date to date of first symptoms or date of sample collection (if subject remained asymptomatic).' answered with 'SUBJECT EXPERIENCED SYMPTOMS OF COUGH, FATIGUE, NEW LOST OF TASTE AND SMELL, NASAL CONGESTION, RUNNY NOSE AND DIARRHEA' (Site from Safety).	Rylea Gulick (b) (4)	29 Sep 2020 20:43:39
User opened query 'PV Query: The event onset date was reported as 04-Sep-2020, however Covid test sample wasn't collected until 08-Sep-2020. Please clarify if the subject was experiencing symptom onset on 04-Sep-2020. If yes, please provide the symptoms. If no, please considering updating event onset date to date of first symptoms or date of sample collection (if subject remained asymptomatic).' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 12:31:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:12:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 19:12:55
User entered '04 Sep 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 19:12:55
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 14:06:56
User entered empty.	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:17
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Oct 2020 21:27:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	29 Sep 2020 20:45:27
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:49:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 16:49:44
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	28 Sep 2020 16:49:44
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 14:06:56
User entered empty.	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:56:21
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '06 Oct 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Oct 2020 21:27:57
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date will be updated with achieved' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:34:44
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date will be updated with achieved' (Site from Safety).	Rylea Gulick (b) (4)	15 Oct 2020 21:04:57
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 14:30:11
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:26:09
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ENTRY WILL BE UPDATED WITH APPLICABLE ' (Site from Safety).	Rylea Gulick (b) (4)	06 Oct 2020 13:24:13
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:57:37
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	29 Sep 2020 20:45:27
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	28 Sep 2020 16:49:44

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). User entered '21 Sep 2020' reason for change: Data Entry Error	System Jamie Thompson (b) (4) (b) (4)	28 Sep 2020 16:49:44 28 Sep 2020 16:49:44
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). User entered empty.	System Jamie Thompson (b) (4) (b) (4)	28 Sep 2020 16:48:55 16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:56:23
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:08:50
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'time not required' (Site from Safety).	Jamie Thompson (b) (4)	28 Sep 2020 16:50:40
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	28 Sep 2020 16:50:27
User entered empty; reason for change Data Entry Error	Jamie Thompson (b) (4)	28 Sep 2020 16:50:27
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	28 Sep 2020 16:50:04
User entered '00:00' reason for change: Data Entry Error	Jamie Thompson (b) (4)	28 Sep 2020 16:50:04
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:41:16
User entered empty.	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:50:27
User entered '21 Sep 2020 00:00'	System	28 Sep 2020 16:50:04
User entered empty.	System	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:56:31
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'PV Query: Please provide the severity of the event.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:58:57
Query 'PV Query: Please provide the severity of the event.' answered with 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4)	29 Sep 2020 20:44:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 20:44:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 20:44:02
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	29 Sep 2020 20:44:02
	(b) (4)	
User opened query 'PV Query: Please provide the severity of the event.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:42:37
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 14:06:56
User entered empty.	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:56:34
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Sep 2020 20:44:02
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	29 Sep 2020 20:44:02
	(b) (4)	
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:09:06
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'Well, you have us enter it as serious; she had mild symptoms and recovered without incident.' (Site from Safety).	Jamie Thompson (b) (4)	28 Sep 2020 16:51:29
	(b) (4)	
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 21:34:33
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:12:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 19:12:55
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Sep 2020 19:12:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 19:12:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 14:06:56
User entered empty.	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:37
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:39
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:44
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:46
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:50
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:53
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:56:54
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:56:56
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
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 02:09:38
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	22 Sep 2020 21:41:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 21:41:47
	(b) (4)	
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 21:34:08
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:12:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 19:12:55
User entered 'Related (RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 19:12:55
	(b) (4)	
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 12:34:32
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 14:06:56
User entered empty.	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:57:01
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:39:32
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'not applicable per pi' (Site from DM).	Rylea Gulick (b) (4)	02 Dec 2020 18:20:28
	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:06:21
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:12:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 19:12:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 19:12:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 14:06:56
User entered empty.	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:57:02
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:46:58
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) (6)	23 Oct 2020 05:49:51
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 'THERE WAS AN OPTION TO SELECT 'DUE TO SARS-COV-2'.' (Site from System).	Rylea Gulick (b) (4) (b) (4)	19 Oct 2020 18:55:03
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	19 Oct 2020 18:54:47
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	19 Oct 2020 18:54:24
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:02:39
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:12:55

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Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 19:12:55
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	22 Sep 2020 19:12:55
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 14:06:56
User entered empty.	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:57:10
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Sep 2020 19:12:55
User entered '1' reason for change: Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 19:12:55
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Sep 2020 14:06:56
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:57:14
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 20:57:15
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Oct 2020 21:27:57
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:34:49
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'end date will be updated when achieved' (Site from Safety).	Rylea Gulick (b) (4)	15 Oct 2020 21:05:06
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 14:30:24
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:26:35
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:57:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	29 Sep 2020 20:45:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:09:10
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'COVID symptoms resolved.' (Site from Safety).	Jamie Thompson (b) (4)	28 Sep 2020 16:49:16
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:48:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 16:48:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	28 Sep 2020 16:48:55
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:41:31
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 14:06:56
User entered empty.	Jamie Thompson (b) (4)	16 Sep 2020 14:06:56

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Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:57:17
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:57:19
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Sep 2020 20:44:02
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	29 Sep 2020 20:44:02
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 19:12:55
User entered empty.	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Sep 2020 20:44:02
User entered '1'	System	22 Sep 2020 19:12:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 14:06:56

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:01:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Sinusitis bacterial, LLT: Sinusitis bacterial - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:41:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:41:45
Data point term sent to Coder	System	29 Sep 2020 21:11:32
User entered 'ACUTE BACTERIAL SINUSITIS'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '18 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
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	29 Sep 2020 21:11:17
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:17
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	29 Sep 2020 21:11:09
User entered '11:00'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
	(b) (4), (b) (6)	
User entered empty.	System	29 Sep 2020 21:11:17
User entered '18 Sep 2020 11:00'	System	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:30:44
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Oct 2020 16:30:53
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	16 Oct 2020 16:30:53
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Oct 2020 16:30:44
User entered '28 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:30:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User entered empty.	(b) (4), (b) (6) System	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

US3042209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

US3042209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

US3042209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

US3042209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

US3042209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

US3042209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Not Related (NOT RELATED)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Not Related (NOT RELATED)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'None (NONE)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:30:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User entered '0'	(b) (4), (b) (6) System	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:07
User entered '1'	(b) (4), (b) (6) System	29 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:52:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:01:07

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:01:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:44:43
User closed query 'Please update to soft tissue injury, left shoulder' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:44:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:17:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:17:37
Data point term sent to Coder	System	06 Apr 2021 19:44:46
Query 'Please update to soft tissue injury, left shoulder' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:44:40
User entered 'SOFT TISSUE INJURY-LEFT SHOULDER' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:44:12
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:43:50
User entered 'SOFT SHOULDER INJURY-LEFT SHOULDER' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:43:50
User opened query 'Please update to soft tissue injury, left shoulder' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:03
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:30:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:30:54
Data point term sent to Coder	System	10 Dec 2020 22:03:21
User entered 'SOFT SHOULD INJURY-LEFT SHOULDER'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '01 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:45:08
User closed query 'Please update, source has event closed' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:45:03
Query 'Please update, source has event closed' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:45:18
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:45:03
User opened query 'Please update, source has event closed' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:12:23
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:54
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:45:10
User closed query 'Please update source has end date 9Dec2020' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:45:06
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Apr 2021 19:45:50
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Apr 2021 19:45:50
Query 'Please update source has end date 9Dec2020' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:45:32
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Apr 2021 19:45:03
User entered '09 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:45:03
User opened query 'Please update source has end date 9Dec2020' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:13:19
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

US3042209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Not Related (NOT RELATED)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered '0'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
User closed query 'Please update' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:45:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:18
Query 'Please update' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:46:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Apr 2021 19:45:50
User opened query 'Please update' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:14:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:13:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:55:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:29:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User entered '0'	(b) (4), (b) (6) System	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:16
User entered '1'	(b) (4), (b) (6) System	10 Dec 2020 22:02:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:52:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:01:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:52:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:07:58
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:30:23
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:35:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:35:48
Data point term sent to Coder	System	02 Oct 2020 19:34:37
Coding entries removed.	Meagan Miller (b) (4)	02 Oct 2020 19:34:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 00:01:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 00:01:52
Data point term sent to Coder	System	03 Sep 2020 00:00:25
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:59:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:24:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'PHENTERMINE'	Coder Import (b) (4) (b) (4) System Rylea Gulick (b) (4) (b) (4)	16 Aug 2020 08:24:10 15 Aug 2020 14:23:36 15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than the action of the medication. Please update as appropriate or provide clarification.' (Site from DM). Query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than the action of the medication. Please update as appropriate or provide clarification.' answered with 'data added' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:09:21
User entered 'obesity' reason for change: Data Entry Error	Meagan Miller (b) (4)	02 Oct 2020 19:34:21
User opened query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than the action of the medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:10:02
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:14:51
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'THERE IS NO EXACT UNDERLYING MEDICAL CONDITION FOR THIS MEDICATION.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 00:00:33
User entered 'APPETITE SUPPRESSANT' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:59:40

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:25:57
User entered 'APPETITE SURPRESSED'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '37.5'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 17:59:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:04
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	15 Aug 2020 14:22:52
User entered 'UN Apr 2020'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 14:22:52

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:24:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:24:25
Data point term sent to Coder	System	15 Aug 2020 14:23:36
User entered 'ESCITALOPRAM'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '20'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 17:59:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4)	15 Aug 2020 14:23:29
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 14:23:23
User entered 'UN UNK 2018'	Rylea Gulick (b) (4)	15 Aug 2020 14:23:23
	(b) (4)	

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 14:23:23

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: LARIN FE 1/20 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:15:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:15:15
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:36:06 07 Nov 2020 15:35:12
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: LARIN FE 1/20 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 11:17:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 11:17:45
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 00:02:26 03 Sep 2020 00:01:55
User entered 'LARIN FE 1/20' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 00:01:55

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: LARIN FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 06:07:29
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 06:07:29
Data point term sent to Coder	System	15 Aug 2020 14:24:37
User entered 'LAREN FE'	Rylea Gulick (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Per DM CLR: Indication = CONTRACEPTION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:42:56
Query 'Per DM CLR: Indication = CONTRACEPTION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:34:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:34:15
User opened query 'Per DM CLR: Indication = CONTRACEPTION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:37:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'CONTRACEPTION' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:35:12
User entered 'CENTRACEPTION'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Per DM CLR: Please note this is a combination drug; however, not all components have been reported in the dose field. Please update the dose to include all components and ensure Dose Unit reported as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:45:59
Query 'Per DM CLR: Please note this is a combination drug; however, not all components have been reported in the dose field. Please update the dose to include all components and ensure Dose Unit reported as appropriate. ' answered with 'DOSAGE UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 00:02:02
User entered '1/0.02' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 00:01:55
User opened query 'Per DM CLR: Please note this is a combination drug; however, not all components have been reported in the dose field. Please update the dose to include all components and ensure Dose Unit reported as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:26:15
User entered '1/20'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 17:59:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4)	15 Aug 2020 14:24:05
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 14:23:56
User entered 'UN Apr 2020'	Rylea Gulick (b) (4)	15 Aug 2020 14:23:56
	(b) (4)	

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 14:23:56

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: MEFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:25:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:25:26
Data point term sent to Coder	System	15 Aug 2020 14:24:38
User entered 'MEFORMIN'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '1000'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'twice daily (BID)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 17:59:56
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:31
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	15 Aug 2020 14:24:25
User entered 'UN UNK 2013'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:03:35
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '22 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:03:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User entered '2'	(b) (4), (b) (6) System	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:46
User entered '804 (804)'	(b) (4), (b) (6) System	15 Aug 2020 14:24:25

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 00:31:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 00:31:21
Data point term sent to Coder	System	15 Aug 2020 14:25:38
User entered 'JAURDIANCE'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '25'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 17:59:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:00
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	15 Aug 2020 14:24:54
User entered 'UN UNK 2019'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:03:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '22 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:03:43
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:51
User entered '804 (804)'	(b) (4), (b) (6) System	15 Aug 2020 14:24:54

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE, PRODUCTSYNONYM: AMARYL [GLIMEPIRIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 23:24:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 23:24:20
Data point term sent to Coder	System	15 Aug 2020 14:25:38
User entered 'AMARYL'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '2'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 18:00:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:24
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	15 Aug 2020 14:25:20
User entered 'UN UNK 2019'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 14:25:20

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 08:38:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 08:38:33
Data point term sent to Coder	System	15 Aug 2020 14:26:45
User entered 'PROPRANLOL'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'MIGRAINE HEADACHES'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '120'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 18:00:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4)	15 Aug 2020 14:25:57
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 14:25:50
User entered 'UN UNK 2019'	Rylea Gulick (b) (4)	15 Aug 2020 14:25:50
	(b) (4)	

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 14:25:50

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: RIZATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:27:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 14:27:11
Data point term sent to Coder	System	15 Aug 2020 14:26:45
User entered 'RIZATRIPTAN'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'MIGRAINE HEADACHES'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '10'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 18:00:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:31
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	15 Aug 2020 14:26:24
User entered 'UN Jan 2020'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 14:26:24

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
Query 'Per DM CLR: Note, this Con Med was added. Please clarify if there was a WORSENING of the Medical History condition requiring an additional medication. If yes, please add the applicable AE entry or explain the reason for additional in regimen. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:37:08
User opened query 'Per DM CLR: Note, this Con Med was added. Please clarify if there was a WORSENING of the Medical History condition requiring an additional medication. If yes, please add the applicable AE entry or explain the reason for additional in regimen. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:36:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: RYBELSUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:05:42
Data point term sent to Coder	System	29 Sep 2020 21:05:19
User entered 'RYBELSUS'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '3'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Per DM CLR: Con Med RYBELSUS was added/changed on 23 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:28:33
Query 'Per DM CLR: Con Med RYBELSUS was added/changed on 23 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'PER PROVIDER, THIS WAS NOT A WORSENING OF MEDICAL CONDITION. ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Oct 2020 19:18:44
User opened query 'Per DM CLR: Con Med RYBELSUS was added/changed on 23 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:37:22
User entered '23 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 21:04:44

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
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)	29 Sep 2020 21:13:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:13:42
Data point term sent to Coder	System	29 Sep 2020 21:12:34
User entered 'AUGMENTIN'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'ACUTE BACTERIAL SINUSITIS'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '875/125'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'twice daily (BID)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '18 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:29:33
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Oct 2020 19:17:09
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Oct 2020 19:17:04
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:18:49
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '28 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Oct 2020 19:17:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User entered '2'	(b) (4), (b) (6) System	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User entered '1'	(b) (4), (b) (6) System	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:20
User entered '804 (804)'	(b) (4), (b) (6) System	29 Sep 2020 21:12:03

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:30:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:30:29
Data point term sent to Coder	System	20 Oct 2020 21:29:51
User entered 'INFLUENZA VACCINE'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'INFLUENZA PROPHYLAXIS'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '.5'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mL (mL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'once (ONCE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Intramuscular (INTRAMUSCULAR)'	Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '08 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '08 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:25
User entered empty.	(b) (4), (b) (6) System	20 Oct 2020 21:28:58

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 11:51:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 11:51:50
Data point term sent to Coder	System	10 Dec 2020 22:04:22
User entered 'TRAMADOL'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'LEFT SHOULDER SOFT TISSUE INJURY'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '50'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '01 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:17:15
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:32
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:32
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:17:15
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	12 Mar 2021 16:00:37
User entered '16 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:37
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	12 Mar 2021 16:00:32
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:32
User entered '16 Dec 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:32
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:34
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 22:03:47

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 16:10:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 16:10:45
Data point term sent to Coder	System	10 Dec 2020 22:04:22
User entered 'METHOCARBAMOL'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'LEFT SHOULDER SOFT TISSUE INJURY'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '750'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '01 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:17:15
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:45
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:45
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:17:15
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:45
User entered '16 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Mar 2021 16:00:45
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:33:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:52:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:40
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 22:04:10

US3042209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:52:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:35:07
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 14:14:35

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'Visit 2 Day 29 (VISIT2)'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'I'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'l'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'l'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'l'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

Central Laboratory - Nasopharyngeal Swab

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'l'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'I'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'l'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'I'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '01 Sep 2020'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'I'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'		
	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered empty.	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'I'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'I'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered 'l'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:52:12

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:43:07
User entered '0'	Rylea Gulick (b) (4)	06 Apr 2021 20:14:10
	(b) (4)	

US3042209

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:52:12

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:18
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:19:42
User entered '08 Sep 2020'	Rylea Gulick (b) (4)	19 Oct 2020 18:54:24
	(b) (4)	

US3042209

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:52:12

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:18
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:15:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:19:42
User entered 'Due to SARS-COV-2 (COVID)'	Rylea Gulick (b) (4)	19 Oct 2020 18:54:24
	(b) (4)	

US3042209

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:52:12

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)	29 Apr 2021 05:09:18
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:15:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:19:42
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Oct 2020 18:54:24

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'USA-US052-2020-MRNA-1273-P301000005'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:25:15
Query 'Please change to PI name, thanks ' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:30
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User opened query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Meagan'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:26:05
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Miller'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '330 dakota dunes suite400'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'North sioux'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'IA'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '57049'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:26:00
User entered 'US' (non-conformant).	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Nov 2020 18:45:53
User entered '6'	System	19 Oct 2020 19:36:11
User entered '5'	System	07 Oct 2020 19:26:57
User entered '4'	System	30 Sep 2020 14:57:26
User entered '3'	System	29 Sep 2020 15:09:36
User entered '2'	System	23 Sep 2020 16:25:57
User entered '1'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'USA-US052-2020-MRNA-1273-P301000005'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:25:15
Query 'Please change to PI name, thanks ' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:30
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User opened query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Meagan'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:26:05
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Miller'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '330 dakota dunes suite400'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'North sioux'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'IA'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '57049'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:26:00
User entered 'US' (non-conformant).	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Nov 2020 18:45:53
User entered '6'	System	19 Oct 2020 19:36:11
User entered '5'	System	07 Oct 2020 19:26:57
User entered '4'	System	30 Sep 2020 14:57:26
User entered '3'	System	29 Sep 2020 15:09:36
User entered '2'	System	23 Sep 2020 16:25:57
User entered '1'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:52:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
User entered '16/Sep/2020 14:14'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:52:12

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.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
User entered 'I'	(b) (4), (b) (6)	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'USA-US052-2020-MRNA-1273-P301000005'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:25:15
Query 'Please change to PI name, thanks ' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:30
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User opened query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Meagan'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:26:05
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Miller'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '330 dakota dunes suite400'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'North sioux'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'IA'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '57049'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:26:00
User entered 'US' (non-conformant).	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Nov 2020 18:45:53
User entered '6'	System	19 Oct 2020 19:36:11
User entered '5'	System	07 Oct 2020 19:26:57
User entered '4'	System	30 Sep 2020 14:57:26
User entered '3'	System	29 Sep 2020 15:09:36
User entered '2'	System	23 Sep 2020 16:25:57
User entered '1'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:52:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
User entered '23/Sep/2020 12:25'	System	23 Sep 2020 16:25:57

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:52:12

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.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 15:09:28
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:25:57

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'USA-US052-2020-MRNA-1273-P301000005'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:25:15
Query 'Please change to PI name, thanks ' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:30
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User opened query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Meagan'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:26:05
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Miller'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '330 dakota dunes suite400'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'North sioux'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'IA'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '57049'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:26:00
User entered 'US' (non-conformant).	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Nov 2020 18:45:53
User entered '6'	System	19 Oct 2020 19:36:11
User entered '5'	System	07 Oct 2020 19:26:57
User entered '4'	System	30 Sep 2020 14:57:26
User entered '3'	System	29 Sep 2020 15:09:36
User entered '2'	System	23 Sep 2020 16:25:57
User entered '1'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:52:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
User entered '29/Sep/2020 11:09'	System	29 Sep 2020 15:09:36

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:52:12

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.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 14:57:09
User entered 'l'	(b) (4), (b) (6)	29 Sep 2020 15:09:36

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'USA-US052-2020-MRNA-1273-P301000005'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:25:15
Query 'Please change to PI name, thanks ' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:30
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User opened query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Meagan'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:26:05
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Miller'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '330 dakota dunes suite400'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'North sioux'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'IA'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '57049'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:26:00
User entered 'US' (non-conformant).	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Nov 2020 18:45:53
User entered '6'	System	19 Oct 2020 19:36:11
User entered '5'	System	07 Oct 2020 19:26:57
User entered '4'	System	30 Sep 2020 14:57:26
User entered '3'	System	29 Sep 2020 15:09:36
User entered '2'	System	23 Sep 2020 16:25:57
User entered '1'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:52:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
User entered '30/Sep/2020 14:57'	System	30 Sep 2020 14:57:26

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:52:12

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.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 19:26:46
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 14:57:26

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'USA-US052-2020-MRNA-1273-P301000005'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:25:15
Query 'Please change to PI name, thanks ' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:30
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User opened query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Meagan'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:26:05
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Miller'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '330 dakota dunes suite400'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'North sioux'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'IA'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '57049'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:26:00
User entered 'US' (non-conformant).	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Nov 2020 18:45:53
User entered '6'	System	19 Oct 2020 19:36:11
User entered '5'	System	07 Oct 2020 19:26:57
User entered '4'	System	30 Sep 2020 14:57:26
User entered '3'	System	29 Sep 2020 15:09:36
User entered '2'	System	23 Sep 2020 16:25:57
User entered '1'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:52:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
User entered '07/Oct/2020 19:26'	System	07 Oct 2020 19:26:57

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:52:12

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.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 19:35:19
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 19:26:57

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'USA-US052-2020-MRNA-1273-P301000005'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:25:15
Query 'Please change to PI name, thanks ' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:30
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User opened query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Meagan'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:26:05
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Miller'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '330 dakota dunes suite400'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'North sioux'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'IA'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '57049'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:26:00
User entered 'US' (non-conformant).	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Nov 2020 18:45:53
User entered '6'	System	19 Oct 2020 19:36:11
User entered '5'	System	07 Oct 2020 19:26:57
User entered '4'	System	30 Sep 2020 14:57:26
User entered '3'	System	29 Sep 2020 15:09:36
User entered '2'	System	23 Sep 2020 16:25:57
User entered '1'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 21:52:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
User entered '19/Oct/2020 19:36'	System	19 Oct 2020 19:36:11

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 21:52:12

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.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:45:37
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 19:36:11

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'USA-US052-2020-MRNA-1273-P301000005'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'No (N)'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
User closed query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:25:15
Query 'Please change to PI name, thanks ' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:30
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User opened query 'Please change to PI name, thanks ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Meagan'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:26:05
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Apr 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'Miller'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:07:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '330 dakota dunes suite400'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'North sioux'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered 'IA'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 18:14:21
User entered '57049'	System	16 Sep 2020 18:13:55

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:25:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:26:00
User entered 'US' (non-conformant).	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Nov 2020 18:45:53
User entered '6'	System	19 Oct 2020 19:36:11
User entered '5'	System	07 Oct 2020 19:26:57
User entered '4'	System	30 Sep 2020 14:57:26
User entered '3'	System	29 Sep 2020 15:09:36
User entered '2'	System	23 Sep 2020 16:25:57
User entered '1'	System	16 Sep 2020 18:14:29

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 11 Aug 2021 21:52:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:16:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:28:24
User entered '19/Nov/2020 13:45'	System	19 Nov 2020 18:45:53

US3042209

Folder: SAE USA-US052-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 11 Aug 2021 21:52:12

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.

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