

US3242002 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:06:10

All time stamps listed in this document are displayed in GMT

US3242002

Form: Participant Creation

Data signed: (b) (4) 31 Aug 2020 13:42:36

Generated On: 11 Aug 2021 22:06:10

Participant ID

US3242002

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

US3242002

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 31 Aug 2020 13:42:36

Generated On: 11 Aug 2021 22:06:10

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

Visit date (dd MMM yyyy)	06 AUG 2020
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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	SCRN
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US3242002

Folder: Screening

Form: Demographics

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Date of Birth (MMM yyyy)	(b) (6) 1984
Age	35
Age Units	YEARS
Age (Derived)	36
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	False
Black	True
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

US3242002

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Date of Informed Consent (*dd MMM yyyy*) 6 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3242002

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Condition	ASTHMA
Start date (dd MMM yyyy)	UN JAN 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242002

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN JAN 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242002

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Condition	DRUG ALLERGY-ASPIRIN
Start date (dd MMM yyyy)	UN JAN 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3242002

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Condition	DRUG ALLERGY-IBUPROFEN
Start date (dd MMM yyyy)	UN JAN 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242002

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Condition	DRUG ALLERGY-ERYTHROMYCIN
Start date (dd MMM yyyy)	UN JAN 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242002

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 31 Aug 2020 13:42:37

Generated On: 11 Aug 2021 22:06:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 AUG 2020
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 09:36
Height (xxx.x)	62 in
Weight (xxx.x)	230 lb
BMI (xxx.x)	42.15551 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242002

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 31 Aug 2020 13:42:34

Generated On: 11 Aug 2021 22:06:10

Date of assessment (dd MMM yyyy) 6 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) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 6 AUG 2020

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 31 Aug 2020 13:42:35

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

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

Visit date (dd MMM yyyy)	06 AUG 2020
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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	VISIT1
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US3242002

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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

What was the participant's randomization number? 143118

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 ☒

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

Height	ND - Not Done
Weight	ND - Not Done

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

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)	6 AUG 2020
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 09:36
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	6 AUG 2020
Time of assessment (00:00-23:59)	16:55 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 16:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3242002

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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.

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

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) _____

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

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

Treatment Date and Time (derived) 06 AUG 2020 16:23

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

US3242002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 6 AUG 2020

Collection time (00:00-23:59) 11:03 (24 HR)

Collection date and time (derived) 6 AUG 2020 11:03

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:03	6 AUG 2020 11:03
Nasopharyngeal Swab 2	No		

US3242002

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 16:57

PC Open Date & Time

06 AUG 2020 16:43

PC Close Date & Time

06 AUG 2020 19:13

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	07 AUG 2020 00:00
PC Open Date & Time	06 AUG 2020 20:08
PC Close Date & Time	07 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:10

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 09:36

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:10

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

96.9 °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

08 AUG 2020 22:08

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:10

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

09 AUG 2020 22:11

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:10

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

99.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 20:21

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

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

100.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 AUG 2020 22:03

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:10

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

99.4 °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

13 AUG 2020 01:27

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 16:57

PC Open Date & Time

06 AUG 2020 16:43

PC Close Date & Time

06 AUG 2020 19:13

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

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

07 AUG 2020 00:00

PC Open Date & Time

06 AUG 2020 20:08

PC Close Date & Time

07 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

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

08 AUG 2020 09:36

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

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

08 AUG 2020 22:08

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 22:12

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 20:21

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 22:04

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 01:27

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 16:58
PC Open Date & Time	06 AUG 2020 16:43
PC Close Date & Time	06 AUG 2020 19:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 00:01
PC Open Date & Time	06 AUG 2020 20:08
PC Close Date & Time	07 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2829

EAB) (1725)

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 09:37
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2829

EAB) (1725)

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 22:08
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2829

EAB) (1725)

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

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 ☒

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 20:22
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2829

EAB) (1725)

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 22:04
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2829

EAB) (1725)

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 01:28
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 13 AUG 2020 21:25

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3242002

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	13 AUG 2020 21:25
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3242002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 31 Aug 2020 13:42:37

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 31 Aug 2020 13:42:37

Generated On: 11 Aug 2021 22:06:10

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
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	

US3242002

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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.

US3242002

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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) _____

US3242002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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? _____

US3242002

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Aug 2020 13:42:34

Generated On: 11 Aug 2021 22:06:10

Was the sample collected? Yes ☐
No ☐

Collection date (dd MMM yyyy) _____

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

Collection date and time (derived) _____

US3242002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

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

SUBJECT DID NOT GET
VACCINE 2 AND WAS NOT
CONTACTED FOR PHONE
CALLS

US3242002

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT DID NOT GET
VACCINE 2, SO CONTACT WAS
NOT DONE

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

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

SUBJECT DID NOT GET
VACCINE 2 AND SUBJECT
WAS WAS CONTACTED FOR
PHONE CALLS

US3242002

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT3

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	15:55 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 15:55
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

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.

US3242002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

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

Collection date (dd MMM yyyy)	29 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	16:18 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	29 SEP 2020 16:18
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US3242002

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:37

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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	06 OCT 2020 21:28:13
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 09:12:24

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 OCT 2020 20:04:32
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 19:27:00
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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	10 NOV 2020 15:28:56
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 11:07:05
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 18:24:28
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 19:58:44
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 09:19:29

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 09:19:07
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

21 DEC 2020 15:39:08

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 13:40:32
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 12:23:38
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 JAN 2021 21:58:34
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

20 JAN 2021 14:48:50

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

26 JAN 2021 18:00:07

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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	01 FEB 2021 21:53:40
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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	08 FEB 2021 16:41:29
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 20:33:47

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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	24 FEB 2021 11:31:21
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

03 MAR 2021 01:43:07

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

08 MAR 2021 17:04:34

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

17 MAR 2021 10:20:54

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 17:16:33
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 21:50:38

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

05 APR 2021 16:56:42

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

14 APR 2021 21:37:54

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

20 APR 2021 08:44:28

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 16:56:47

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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°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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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°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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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="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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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°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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐ 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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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°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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐
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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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="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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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="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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 ☐ 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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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°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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3242002

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:06:10

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		03 MAR 2021 01:43:20

US3242002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 11 Mar 2021 00:24:42

Generated On: 11 Aug 2021 22:06:10

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

Visit date (dd MMM yyyy)	08 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:37:44

Generated On: 11 Aug 2021 22:06:10

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) _____

US3242002

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 11 Mar 2021 00:24:42

Generated On: 11 Aug 2021 22:06:10

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.

US3242002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 11 Mar 2021 00:24:42

Generated On: 11 Aug 2021 22:06:10

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

Collection date (dd MMM yyyy)	08 MAR 2021
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Collection time (00:00-23:59)	16:35 (24 HR)
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Collection date and time (derived)	08 MAR 2021 16:35
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US3242002

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 00:24:42

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 14:41:40

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 14:41:40

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:08:50

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:08:50

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Date of Contact	10 AUG 2020
Time of Contact	22:05
Date and Time of Contact (derived)	10 AUG 2020 22:05
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

Symptom Day

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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 10 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	10 AUG 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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 10 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	11 AUG 2020
------	-------------

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

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

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

Temperature	99.1 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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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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 10 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	12 AUG 2020
------	-------------

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

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

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

Temperature	100.3 F
-------------	---------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 AUG 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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 10 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	18 AUG 2020
------	-------------

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

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

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

Temperature	98.7 F
-------------	--------

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

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

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

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

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Form: Symptom Log (10)

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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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Form: Symptom Log (10)

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Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Mar 2021 12:24:20

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input 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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Form: Symptom Log (11)

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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	19 AUG 2020
------	-------------

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

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

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

Temperature	98.8 F
-------------	--------

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

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 17 Mar 2021 12:24:20

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input 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) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	20 AUG 2020
------	-------------

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

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

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

Temperature	98.7 F
-------------	--------

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

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

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

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

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Form: Symptom Log (12)

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Generated On: 11 Aug 2021 22:06:10

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

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Form: Symptom Log (12)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Form: Symptom Log (13)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Form: Symptom Log (13)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 (14)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	22 AUG 2020
------	-------------

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

O2 Saturation	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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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	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 (14)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	23 AUG 2020
------	-------------

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

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

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

Temperature	99.2 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

Symptom Day

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	25 AUG 2020
------	-------------

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

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

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

Temperature	99 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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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input 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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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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 10 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

Symptom Day

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

Symptom Day

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	30 AUG 2020
------	-------------

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

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

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

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

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

Cough	None <input 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 (22)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 (23)

Data signed: (b) (4) 17 Mar 2021 12:24:20

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input 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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Form: Symptom Log (23)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	31 AUG 2020
------	-------------

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

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

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

Temperature	99.1 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	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 (23)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

Date	01 SEP 2020
------	-------------

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

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

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

Temperature	99.1 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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US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

	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"/>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) 17 Mar 2021 12:24:20

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 25 Mar 2021 18:09:01

Generated On: 11 Aug 2021 22:06:10

Date of Visit 12 AUG 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Date of Test 12 AUG 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Feb 2021 17:58:34

Generated On: 11 Aug 2021 22:06:10

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Feb 2021 17:58:34

Generated On: 11 Aug 2021 22:06:10

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Feb 2021 17:58:34

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 08 Feb 2021 17:58:34

Generated On: 11 Aug 2021 22:06:10

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 08 Feb 2021 17:58:33

Generated On: 11 Aug 2021 22:06:10

Date of Contact	10 AUG 2020
Time of Contact	22:05
Date and Time of Contact (derived)	10 AUG 2020 22:05
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 08 Feb 2021 17:58:33

Generated On: 11 Aug 2021 22:06:10

Date of Visit 12 AUG 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Date of Test 12 AUG 2020

Type of Test Performed Nasopharyngeal Swab ☐
Nasal Swab ☐
Saliva Test ☒
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Mar 2021 22:00:12

Generated On: 11 Aug 2021 22:06:10

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 _____

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Mar 2021 22:00:12

Generated On: 11 Aug 2021 22:06:10

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

ECMO? Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Mar 2021 22:00:12

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 08 Feb 2021 17:58:35

Generated On: 11 Aug 2021 22:06:10

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 AUG 2020
Day 5	Yes	16 AUG 2020
Day 7	Yes	18 AUG 2020
Day 9	Yes	21 AUG 2020
Day 14	Yes	26 AUG 2020
Day 21	Yes	1 SEP 2020
Day 28	Yes	8 SEP 2020

US3242002

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 31 Aug 2020 13:42:37

Generated On: 11 Aug 2021 22:06:10

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

Visit date (dd MMM yyyy)	12 AUG 2020
--------------------------	-------------

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

Folder OID	SICKD1
------------	--------

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Aug 2020 13:42:37

Generated On: 11 Aug 2021 22:06:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	17:46 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 17:46
Height (xxx.x)	62 in
Weight (xxx.x)	230 lb
Temperature (xxx.x)	99.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	116 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242002

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3242002

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 AUG 2020

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 17:58:33

Generated On: 11 Aug 2021 22:06:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 17:58:33

Generated On: 11 Aug 2021 22:06:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:01
Height (xxx.x)	62 in
Weight (xxx.x)	230 lb
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 17:58:33

Generated On: 11 Aug 2021 22:06:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3242002

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 08 Feb 2021 17:58:33

Generated On: 11 Aug 2021 22:06:10

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 SEP 2020

US3242002

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

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 12 JAN 2021

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

Folder OID UNBLND_DECIDE

US3242002

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 15:54:41

Generated On: 11 Aug 2021 22:06:10

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3242002

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

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

US3242002

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

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)	12 JAN 2021
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 16:52
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3242002

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

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)	12 JAN 2021
Time of assessment (00:00-23:59)	18:12 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 18:12
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3242002

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

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 17:58:35

Generated On: 11 Aug 2021 22:06:10

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.

US3242002

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

Form: Pregnancy Test

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 12 JAN 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☐

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

US3242002

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

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 17:58:35

Generated On: 11 Aug 2021 22:06:10

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 JAN 2021

What was the treatment time? (00:00-23:59) 17:40 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 17:40

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

US3242002

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 17:58:35

Generated On: 11 Aug 2021 22:06:10

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00-23:59)	16:27 (24 HR)
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Collection date and time (derived)	12 JAN 2021 16:27
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US3242002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Feb 2021 17:58:35

Generated On: 11 Aug 2021 22:06:10

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00 - 23:59)	16:16
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Collection Date and Time (derived)	12 JAN 2021 16:16
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US3242002

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

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:35

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 17:19:05

Generated On: 11 Aug 2021 22:06:10

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

Visit date (dd MMM yyyy)	15 FEB 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	OLD29
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US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 17:19:05

Generated On: 11 Aug 2021 22:06:10

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)	15 FEB 2021
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 16:52
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 17:19:05

Generated On: 11 Aug 2021 22:06:10

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)	15 FEB 2021
Time of assessment (00:00-23:59)	18:12 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 18:12
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3242002

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 17:19:05

Generated On: 11 Aug 2021 22:06:10

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.

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 17:19:05

Generated On: 11 Aug 2021 22:06:10

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 15 FEB 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3242002

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 17:19:05

Generated On: 11 Aug 2021 22:06:10

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) 15 FEB 2021

What was the treatment time? (00:00-23:59) 17:40 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 17:40

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

US3242002

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 17:19:05

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 22:00:12

Generated On: 11 Aug 2021 22:06:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3242002

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 22:00:12

Generated On: 11 Aug 2021 22:06:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242002

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 11 Mar 2021 00:24:42

Generated On: 11 Aug 2021 22:06:10

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

Visit date (dd MMM yyyy)	08 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	OLD57
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US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 11 Mar 2021 00:24:42

Generated On: 11 Aug 2021 22:06:10

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) _____

US3242002

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 11 Mar 2021 00:24:42

Generated On: 11 Aug 2021 22:06:10

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.

US3242002

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 11 Mar 2021 00:24:42

Generated On: 11 Aug 2021 22:06:10

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

Collection date (dd MMM yyyy)	08 MAR 2021
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Collection time (00:00-23:59)	16:35 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	08 MAR 2021 16:35
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US3242002

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Aug 2020 13:42:34

Generated On: 11 Aug 2021 22:06:10

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Feb 2021 17:58:30

Generated On: 11 Aug 2021 22:06:10

AEID	USA-US067-2020-MRNA-1273-P30 1000001
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	09 AUG 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)	02 SEP 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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Feb 2021 17:58:30

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Feb 2021 17:58:30

Generated On: 11 Aug 2021 22:06:10

SUBJECT WAS NEGATIVE AT
BASELINE SWAB AND REPORTS
THAT SHE WAS NOT IN
CONTACT WITH ANYONE THAT
HAD COVID SYMPTOMS.

SUBJECT STATES HER
SYMPTOMS STARTED ON AUG
9, AFTER SHE HAD COMPLETED
HER DIARY, SO SYMPTOMS
WERE NOT RECORDED IN
DIARY ON AUG 9. START DATE
OF AE WILL BE AUG 9, SINCE
THAT IS WHEN SHE SAID THE
COUGH AND SNEEZING
INITIALLY STARTED. (THIS IS
PER COORDINATOR SOURCE
PROGRESS NOTE)

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)	

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Feb 2021 17:58:30

Generated On: 11 Aug 2021 22:06:10

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 AUG 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)	13 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Feb 2021 17:58:30

Generated On: 11 Aug 2021 22:06:10

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Feb 2021 17:58:30

Generated On: 11 Aug 2021 22:06:10

AEID	
Adverse event	SNEEZING
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	9 AUG 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)	11 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Feb 2021 17:58:30

Generated On: 11 Aug 2021 22:06:10

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

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

Yes ☒

No ☐

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

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 90

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) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 1990	
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"/>

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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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US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

Name of Medication DEPO PROVERA

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 104

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

EVERY 3 MONTH

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

	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 OCT 2012
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"/>

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 50

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

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EAB) (1725)

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIC RHINITIS

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

	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 JAN 1990
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"/>

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

Name of Medication FLOVENT HFA

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 110

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

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

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19 (SYMPTOMS)

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

Name of Medication BACTRIM DS1

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 160/800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Feb 2021 17:58:32

Generated On: 11 Aug 2021 22:06:10

	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)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3242002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 08 Feb 2021 17:58:35

Generated On: 11 Aug 2021 22:06:10

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	False
Medical History Summary	False
Medical History	False
Vital Signs	True
Vital Signs - Dosing	True
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	True
Childbearing Potential	False
Pregnancy Test	False
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	True
Dosing Discontinuation	False

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 08 Feb 2021 17:58:35

Generated On: 11 Aug 2021 22:06:10

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	1 SEP 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	True
Missed Assessment	True
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	True
Other, specify	PC D36, D43, D50 WERE AFFECTED.
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3242002

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Date of dosing discontinuation (dd MMM yyyy) 26 AUG 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 31 Aug 2020 13:42:35

Generated On: 11 Aug 2021 22:06:10

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<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"/>
Other	<input type="checkbox"/>

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	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

SAEID	USA-US067-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

SAEID	USA-US067-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/AUG/2020 10:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

SAEID	USA-US067-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/AUG/2020 14:46
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

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Feb 2021 17:58:36

Generated On: 11 Aug 2021 22:06:10

SAEID	USA-US067-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/SEP/2020 21:16
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

US3242002 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242002

Form: Participant Creation

Generated On: 11 Aug 2021 22:06:10

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:59:37
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'US3242002'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:14:33

US3242002

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 16:59:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:10

US3242002

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 16:59:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:14:34

US3242002

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 16:59:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:10

US3242002

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'SCRN'	(b) (4), (b) (6) System	06 Aug 2020 14:57:10

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered (b) (6) 1984'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:14:35

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '35'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'YEARS'	(b) (4), (b) (6) System	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '36'	(b) (4), (b) (6) System	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Female (F)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:10

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:33

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '6 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Aug 2020'	(b) (4), (b) (6) System	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '2020'	(b) (4), (b) (6) System	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Amendment 1 (1)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:46

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:14:34

US3242002

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'I'	(b) (4), (b) (6) System	06 Aug 2020 14:57:51

US3242002

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:00:40
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:57:51

US3242002

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:06:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:23
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:58:03

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 14:59:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 14:59:14
Data point term sent to Coder	System	06 Aug 2020 14:58:26
User entered 'Asthma'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'UN Jan 1985'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Jan 1985'	(b) (4), (b) (6) System	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '1985'	(b) (4), (b) (6) System	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 14:58:25

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:01:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:01:21
Data point term sent to Coder	System	06 Aug 2020 15:00:28
User entered 'Seasonal allergic rhinitis'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'UN Jan 1985'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Jan 1985'	(b) (4), (b) (6) System	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '1985'	(b) (4), (b) (6) System	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 14:59:38

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:01:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:01:23
Data point term sent to Coder	System	06 Aug 2020 15:00:30
User entered 'Obesity'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'UN Aug 2010'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Aug 2010'	(b) (4), (b) (6) System	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '2010'	(b) (4), (b) (6) System	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:00:14

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:02:10
Data point term sent to Coder	System	06 Aug 2020 15:01:33
User entered 'Insomnia'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'UN UNK 2015'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Jan 2015'	(b) (4), (b) (6) System	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '2015'	(b) (4), (b) (6) System	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:00:34

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:02:10
Data point term sent to Coder	System	06 Aug 2020 15:01:35
User entered 'Anxiety'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'UN Jan 2015'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Jan 2015'	(b) (4), (b) (6) System	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '2015'	(b) (4), (b) (6) System	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:01:14

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:35:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:35:17
Data point term sent to Coder	System	06 Aug 2020 15:03:38
User entered 'Drug allergy-Aspirin'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'UN Jan 2014'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Jan 2014'	(b) (4), (b) (6) System	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '2014'	(b) (4), (b) (6) System	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:03:07

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	25 Jan 2021 14:12:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	25 Jan 2021 14:12:50 10 Nov 2020 14:37:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 10:44:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. User signature succeeded.	Coder Import (b) (4) (b) (4) Nathan Segall (b) (4) (b) (4)	04 Sep 2020 10:44:36 31 Aug 2020 13:42:38
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:37:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder User entered 'Drug allergy-Ibuprofen'	Coder Import (b) (4) (b) (4) System Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 06:37:22 06 Aug 2020 15:03:38 06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'UN Jan 2014'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Jan 2014'	(b) (4), (b) (6) System	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '2014'	(b) (4), (b) (6) System	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:03:25

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:36:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:36:20
Data point term sent to Coder	System	06 Aug 2020 15:04:43
User entered 'Drug allergy-Erythromycin'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'UN Jan 1985'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:37:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'Jan 1985'	(b) (4), (b) (6) System	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '1985'	(b) (4), (b) (6) System	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:03:51

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '6 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '09:36'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '6 Aug 2020 09:36'	(b) (4), (b) (6) System	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '62' in	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04
DataPoint set to visible.	System	06 Aug 2020 14:57:51

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '230' lb	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04
DataPoint set to visible.	System	06 Aug 2020 14:57:51

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
Amendment Manager: User entered '42.15551'	(b) (4), (b) (6)	
User entered '42.2'	System	16 Sep 2020 23:45:03
DataPoint set to visible.	System	06 Aug 2020 15:05:04
	System	06 Aug 2020 14:57:51

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'kg/m2'	(b) (4), (b) (6)	06 Aug 2020 15:05:04
DataPoint set to visible.	System	06 Aug 2020 14:57:51

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 12:22:51
User entered '97.3' F	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 12:22:51
User entered 'Oral (Oral)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 12:22:51
User entered '76'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'bpm'	(b) (4), (b) (6) System	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 12:22:51
User entered '16'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'breaths/min'	(b) (4), (b) (6) System	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 12:22:51
User entered '122'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:01:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 12:22:51
User entered '76'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 15:05:04

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 10:36:40

US3242002

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 10:36:40

US3242002

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:06:47

US3242002

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:07
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 14:37:26
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 22:34:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 12:50:25
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 22:29:45
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 22:29:45
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 22:29:45
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	25 Aug 2020 22:29:45
User entered '06 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	25 Aug 2020 22:29:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 22:29:37
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 22:29:37

US3242002

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Physical Examination Date is System prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		25 Aug 2020 22:29:37
User opened query 'The physical examination date is System before the Date of Informed Consent. Please review and reconcile.' (Site from System).		25 Aug 2020 22:29:37
User closed query 'The Physical Examination Date is System prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		25 Aug 2020 22:29:37
User entered '05 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	25 Aug 2020 22:29:37
User opened query 'The Physical Examination Date is System prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		24 Aug 2020 21:06:16
User closed query 'The Physical Examination Date is System prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		24 Aug 2020 21:06:16
User entered '06 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:06:16
User opened query 'The Physical Examination Date is System prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		24 Aug 2020 21:02:10
User entered '6 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:06:47

US3242002

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '6 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:07:37

US3242002

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:06:10

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:07:37

US3242002

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:06:10

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:07:37

US3242002

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:06:10

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:07:37

US3242002

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:06:10

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:07:37

US3242002

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:06:10

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:07:37

US3242002

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:06:10

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:07:37

US3242002

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:06:10

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 15:07:37

US3242002

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:09

US3242002

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '6 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:09

US3242002

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Urine (URINE)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:09

US3242002

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Negative (NEGATIVE)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:09

US3242002

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:09

US3242002

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:09

US3242002

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:42:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:09

US3242002

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 20:27:09

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 20:27:58
	(b) (4)	

US3242002

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:45:50
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:27:58

US3242002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:37:12
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 15:25:39
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:37:12
Signature has been broken.	Donna Toepfer (b) (4)	09 Nov 2020 22:32:38
	(b) (4)	
User entered '06 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 22:32:38
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 15:25:39
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:37:12
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	06 Aug 2020 15:25:39
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'VISIT1'	(b) (4), (b) (6) System	06 Aug 2020 15:25:39

US3242002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 15:14:25
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:26:50
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:26:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 15:14:25
User entered '143118' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 15:14:25

US3242002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT	06 Aug 2020 15:14:25
	ENDPOINT (b) (4)	
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:10

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)	03 Apr 2021 15:45:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 20:28:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:10

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)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 20:28:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 20:28:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:10

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 20:28:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 20:28:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
Signature has been broken.	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	24 Aug 2020 12:22:09
	(b) (4)	
User entered '62' in	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
Signature has been broken.	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	24 Aug 2020 12:22:09
	(b) (4)	
User entered '230' lb	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
Signature has been broken.	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	24 Aug 2020 12:22:09
	(b) (4)	
User entered '62' in	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
Signature has been broken.	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	24 Aug 2020 12:22:09
	(b) (4)	
User entered '230' lb	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '09:36'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered '6 Aug 2020 09:36'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '97.3' F	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '76'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'bpm'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '16'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'breaths/min'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '122'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '76'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
Signature has been broken.	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	24 Aug 2020 12:22:09
	(b) (4)	
User entered '62' in	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
Signature has been broken.	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 19:29:14
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	24 Aug 2020 12:22:09
	(b) (4)	
User entered '230' lb	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
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)	10 Aug 2020 07:25:59
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 30 mins' (Site from System).	Donna Toepfer (b) (4)	06 Aug 2020 22:26:10
	(b) (4)	
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).		06 Aug 2020 22:25:52
User entered '16:55'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered '6 Aug 2020 16:55'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '98.3' F	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '97'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'bpm'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '18'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'breaths/min'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '122'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 13:40:43
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '73'	Donna Toepfer (b) (4)	06 Aug 2020 22:25:52
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 22:25:52

US3242002

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:42:50
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 15:26:17
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:42:50
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 15:26:17
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:03
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 15:27:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:03
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 15:27:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:03
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 15:27:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:03
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 15:27:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:03
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	24 Sep 2020 13:00:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	24 Sep 2020 13:00:20
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 15:27:07
	(b) (4)	
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:03
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 15:27:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:03
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 15:27:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:27:07

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:44
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 20:29:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:44
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 20:29:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:44
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 20:29:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:26:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:44
Query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:41:58
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:41:50
User entered '06 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:41:50
User opened query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:06:49
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '6 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	06 Aug 2020 20:29:33

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:44
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '16:23'	Donna Toepfer (b) (4)	06 Aug 2020 20:29:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered '06 Aug 2020 16:23'	(b) (4), (b) (6)	
	System	09 Nov 2020 13:41:50
User entered '6 Aug 2020 16:23'	System	06 Aug 2020 20:29:33

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:44
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	06 Aug 2020 20:29:33
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:01:44
User entered 'ONCE'	System	06 Aug 2020 20:29:33

US3242002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:18
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 20:29:50
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:18
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 20:29:50
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:48:28
	(b) (4)	
DataPoint Un-verified.	Erynn McKinley (b) (4)	19 Nov 2020 15:49:33
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 15:49:33
	(b) (4)	
User entered '11:03' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 15:49:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:18
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
	(b) (4)	
User entered '11:05'	Donna Toepfer (b) (4)	06 Aug 2020 20:29:50
	(b) (4)	
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User entered '6 Aug 2020 11:03'	System	19 Nov 2020 15:49:33
User entered '6 Aug 2020 11:05'	System	06 Aug 2020 20:29:50

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:43:32
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 20:30:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	06 Aug 2020 20:30:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:07
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 20:30:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:07
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '11:03'	Donna Toepfer (b) (4)	06 Aug 2020 20:30:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered '6 Aug 2020 11:03'	(b) (4), (b) (6) System	06 Aug 2020 20:30:07

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	06 Aug 2020 20:30:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:07
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 20:30:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:07
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 20:30:07
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 20:30:07

US3242002

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:46:08
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 20:30:54
	(b) (4)	

US3242002

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered '1'	(b) (4), (b) (6) System	06 Aug 2020 20:30:54

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:00', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0a218d76-2359-4a2c-9e27-6ba4a9808186'	(b) (4), (b) (6) System	06 Aug 2020 20:57:22
User entered 'Yes (Y)'	System	06 Aug 2020 20:57:22

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:07', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0a218d76-2359-4a2c-9e27-6ba4a9808186' User entered '98.3'	(b) (4), (b) (6) System	06 Aug 2020 20:57:22
	System	06 Aug 2020 20:57:22

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:12', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0a218d76-2359-4a2c-9e27-6ba4a9808186'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Aug 2020 20:57:22

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:18', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0a218d76-2359-4a2c-9e27-6ba4a9808186'	(b) (4), (b) (6) System	06 Aug 2020 20:57:22
User entered '06 Aug 2020 16:57'	System	06 Aug 2020 20:57:22

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '06 Aug 2020 16:43'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '06 Aug 2020 19:13'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T23:59:24', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '32b9e5cf-8cd6-465b-afc1-a970834c34d9'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	07 Aug 2020 04:00:36

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:21', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '32b9e5cf-8cd6-465b-afc1-a970834c34d9'	(b) (4), (b) (6)	
User entered '97.5'	System	07 Aug 2020 04:00:36

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:25', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '32b9e5cf-8cd6-465b-afc1-a970834c34d9'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Aug 2020 04:00:36

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:29', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '32b9e5cf-8cd6-465b-afc1-a970834c34d9'	(b) (4), (b) (6) System	07 Aug 2020 04:00:36
User entered '07 Aug 2020 00:00'	System	07 Aug 2020 04:00:36

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '06 Aug 2020 20:08'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 2'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:34:56', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '83551620-97df-4780-a1c5-7ab2b7347696'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	08 Aug 2020 13:36:37

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '83551620-97df-4780-a1c5-7ab2b7347696'	(b) (4), (b) (6)	
User entered '97.2'	System	08 Aug 2020 13:36:37

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:30', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '83551620-97df-4780-a1c5-7ab2b7347696'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Aug 2020 13:36:37

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '83551620-97df-4780-a1c5-7ab2b7347696'	(b) (4), (b) (6) System	08 Aug 2020 13:36:37
User entered '08 Aug 2020 09:36'	System	08 Aug 2020 13:36:37

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '07 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 3'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:07:32', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'dba64add-e875-44d3-a796-d0aec88bbeb0'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	09 Aug 2020 02:08:28

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:17', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'dba64add-e875-44d3-a796-d0aec88bbeb0'	(b) (4), (b) (6)	
User entered '96.9'	System	09 Aug 2020 02:08:28

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:21', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'dba64add-e875-44d3-a796-d0aec88bbeb0'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Aug 2020 02:08:28

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:24', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'dba64add-e875-44d3-a796-d0aec88bbeb0'	(b) (4), (b) (6) System	09 Aug 2020 02:08:28
User entered '08 Aug 2020 22:08'	System	09 Aug 2020 02:08:28

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 4'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:11:41', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8bc23270-8793-4628-bd93-b850d401a454'	(b) (4), (b) (6) System	10 Aug 2020 02:11:55
User entered 'Yes (Y)'	System	10 Aug 2020 02:11:55

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:11:44', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8bc23270-8793-4628-bd93-b850d401a454'	(b) (4), (b) (6) System	10 Aug 2020 02:11:55
User entered '98.1'	System	10 Aug 2020 02:11:55

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:11:48', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8bc23270-8793-4628-bd93-b850d401a454'	(b) (4), (b) (6) System	10 Aug 2020 02:11:55
User entered 'No (N)'	System	10 Aug 2020 02:11:55

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:11:51', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8bc23270-8793-4628-bd93-b850d401a454'	(b) (4), (b) (6) System	10 Aug 2020 02:11:55
User entered '09 Aug 2020 22:11'	System	10 Aug 2020 02:11:55

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 5'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:05', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '386b386e-b270-44ce-b570-5fc589ae7189'	(b) (4), (b) (6) System	11 Aug 2020 00:21:21
User entered 'Yes (Y)'	System	11 Aug 2020 00:21:21

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:10', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '386b386e-b270-44ce-b570-5fc589ae7189' User entered '99.7'	(b) (4), (b) (6) System	11 Aug 2020 00:21:21
	System	11 Aug 2020 00:21:21

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:13', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '386b386e-b270-44ce-b570-5fc589ae7189'	(b) (4), (b) (6) System	11 Aug 2020 00:21:21
User entered 'No (N)'	System	11 Aug 2020 00:21:21

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:18', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '386b386e-b270-44ce-b570-5fc589ae7189'	(b) (4), (b) (6) System	11 Aug 2020 00:21:21
User entered '10 Aug 2020 20:21'	System	11 Aug 2020 00:21:21

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 6'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:32', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a00514f3-4983-46e0-9eae-2c4288ca2f4b'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Aug 2020 02:03:56

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:38', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a00514f3-4983-46e0-9eae-2c4288ca2f4b' User entered '100.3'	(b) (4), (b) (6) System	12 Aug 2020 02:03:56
	System	12 Aug 2020 02:03:56

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:41', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a00514f3-4983-46e0-9eae-2c4288ca2f4b'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Aug 2020 02:03:56

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted, and conmeds were updated.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 11:02:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Grace Newville (b) (4)	12 Aug 2020 13:55:34
	(b) (4)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:46', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a00514f3-4983-46e0-9eae-2c4288ca2f4b'		
User entered '1'	System	12 Aug 2020 02:03:56
	System	12 Aug 2020 02:03:56
	System	12 Aug 2020 02:03:56

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:46', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a00514f3-4983-46e0-9eae-2c4288ca2f4b'	(b) (4), (b) (6)	
User entered '0'	System	12 Aug 2020 02:03:56

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:50', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a00514f3-4983-46e0-9eae-2c4288ca2f4b'	(b) (4), (b) (6) System	12 Aug 2020 02:03:56
User entered '11 Aug 2020 22:03'	System	12 Aug 2020 02:03:56

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 7'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:00', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '4f276f51-f34e-4fdc-8cb6-a39fdb175388'	(b) (4), (b) (6) System	13 Aug 2020 05:27:22
User entered 'Yes (Y)'	System	13 Aug 2020 05:27:22

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:04', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '4f276f51-f34e-4fdc-8cb6-a39fdb175388'	(b) (4), (b) (6)	
User entered '99.4'	System	13 Aug 2020 05:27:22

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:08', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '4f276f51-f34e-4fdc-8cb6-a39fdb175388'	(b) (4), (b) (6) System	13 Aug 2020 05:27:22
User entered 'No (N)'	System	13 Aug 2020 05:27:22

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:17', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '4f276f51-f34e-4fdc-8cb6-a39fdb175388'	(b) (4), (b) (6) System	13 Aug 2020 05:27:22
User entered '13 Aug 2020 01:27'	System	13 Aug 2020 05:27:22

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:31', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a413ad2d-ee91-4a50-abbc-2cf5da469595'	(b) (4), (b) (6) System	06 Aug 2020 20:58:02
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 20:58:02

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:40', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a413ad2d-ee91-4a50-abb0-2cf5da469595'	(b) (4), (b) (6) System	06 Aug 2020 20:58:02
User entered 'No (N)'	System	06 Aug 2020 20:58:02

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:48', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a413ad2d-ee91-4a50-abb-2cf5da469595'	(b) (4), (b) (6) System	06 Aug 2020 20:58:02
User entered 'No (N)'	System	06 Aug 2020 20:58:02

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:52', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a413ad2d-ee91-4a50-abbc-2cf5da469595'	(b) (4), (b) (6) System	06 Aug 2020 20:58:02
User entered 'None (1)'	System	06 Aug 2020 20:58:02

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:57:58', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a413ad2d-ee91-4a50-abb0-2cf5da469595'	(b) (4), (b) (6) System	06 Aug 2020 20:58:02
User entered '06 Aug 2020 16:57'	System	06 Aug 2020 20:58:02

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '06 Aug 2020 16:43'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '06 Aug 2020 19:13'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:41', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '31330417-d5af-48e9-bd42-2971021cb4fc'	(b) (4), (b) (6) System	07 Aug 2020 04:00:55
User entered 'None (1)'	System	07 Aug 2020 04:00:55

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:43', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '31330417-d5af-48e9-bd42-2971021cb4fc'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Aug 2020 04:00:55

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:45', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '31330417-d5af-48e9-bd42-2971021cb4fc'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Aug 2020 04:00:55

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:47', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '31330417-d5af-48e9-bd42-2971021cb4fc'	(b) (4), (b) (6) System	07 Aug 2020 04:00:55
User entered 'None (1)'	System	07 Aug 2020 04:00:55

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:51', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '31330417-d5af-48e9-bd42-2971021cb4fc'	(b) (4), (b) (6) System	07 Aug 2020 04:00:55
User entered '07 Aug 2020 00:00'	System	07 Aug 2020 04:00:55

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '06 Aug 2020 20:08'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 2'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:40', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3d8596e9-277b-4fa2-98ae-9b890c702b2f'	(b) (4), (b) (6)	
	System	08 Aug 2020 13:36:59
User entered 'None (1)'	System	08 Aug 2020 13:36:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:47', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3d8596e9-277b-4fa2-98ae-9b890c702b2f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Aug 2020 13:36:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:49', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3d8596e9-277b-4fa2-98ae-9b890c702b2f'	(b) (4), (b) (6) System	08 Aug 2020 13:36:59
User entered 'No (N)'	System	08 Aug 2020 13:36:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:52', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3d8596e9-277b-4fa2-98ae-9b890c702b2f'	(b) (4), (b) (6)	
	System	08 Aug 2020 13:36:59
User entered 'None (1)'	System	08 Aug 2020 13:36:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:55', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3d8596e9-277b-4fa2-98ae-9b890c702b2f'	(b) (4), (b) (6) System	08 Aug 2020 13:36:59
User entered '08 Aug 2020 09:36'	System	08 Aug 2020 13:36:59

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '07 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 3'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'd8b0edcf-3346-4f5b-b438-2f9954ec3043'	(b) (4), (b) (6) System	09 Aug 2020 02:08:40
User entered 'None (1)'	System	09 Aug 2020 02:08:40

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:30', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'd8b0edcf-3346-4f5b-b438-2f9954ec3043'	(b) (4), (b) (6) System	09 Aug 2020 02:08:40
User entered 'No (N)'	System	09 Aug 2020 02:08:40

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:31', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'd8b0edcf-3346-4f5b-b438-2f9954ec3043'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Aug 2020 02:08:40

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'd8b0edcf-3346-4f5b-b438-2f9954ec3043'	(b) (4), (b) (6) System	09 Aug 2020 02:08:40
User entered 'None (1)'	System	09 Aug 2020 02:08:40

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:37', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'd8b0edcf-3346-4f5b-b438-2f9954ec3043'	(b) (4), (b) (6) System	09 Aug 2020 02:08:40
User entered '08 Aug 2020 22:08'	System	09 Aug 2020 02:08:40

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 4'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:11:55', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9eb61ebe-0dd8-42cd-8ef0-7ad6f804e04f'	(b) (4), (b) (6) System	10 Aug 2020 02:12:18
User entered 'None (1)'	System	10 Aug 2020 02:12:18

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:01', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9eb61ebe-0dd8-42cd-8ef0-7ad6f804e04f'	(b) (4), (b) (6) System	10 Aug 2020 02:12:18
User entered 'No (N)'	System	10 Aug 2020 02:12:18

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:03', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9eb61ebe-0dd8-42cd-8ef0-7ad6f804e04f'	(b) (4), (b) (6) System	10 Aug 2020 02:12:18
User entered 'No (N)'	System	10 Aug 2020 02:12:18

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:11', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9eb61ebe-0dd8-42cd-8ef0-7ad6f804e04f'	(b) (4), (b) (6) System	10 Aug 2020 02:12:18
User entered 'None (1)'	System	10 Aug 2020 02:12:18

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:14', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9eb61ebe-0dd8-42cd-8ef0-7ad6f804e04f'	(b) (4), (b) (6) System	10 Aug 2020 02:12:18
User entered '09 Aug 2020 22:12'	System	10 Aug 2020 02:12:18

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 5'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:24', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '024af261-1078-4dcd-b1b4-3935a63f7dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:21:37
User entered 'None (1)'	System	11 Aug 2020 00:21:37

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:26', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '024af261-1078-4dcd-b1b4-3935a63f7dfa'	(b) (4), (b) (6)	
	System	11 Aug 2020 00:21:37
User entered 'No (N)'	System	11 Aug 2020 00:21:37

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '024af261-1078-4dcd-b1b4-3935a63f7dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:21:37
User entered 'No (N)'	System	11 Aug 2020 00:21:37

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:31', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '024af261-1078-4dcd-b1b4-3935a63f7dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:21:37
User entered 'None (1)'	System	11 Aug 2020 00:21:37

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '024af261-1078-4dcd-b1b4-3935a63f7dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:21:37
User entered '10 Aug 2020 20:21'	System	11 Aug 2020 00:21:37

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 6'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:53', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3b9c48aa-c904-4f5b-87a5-f4dbc23e23a5'	(b) (4), (b) (6) System	12 Aug 2020 02:04:08
User entered 'None (1)'	System	12 Aug 2020 02:04:08

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:55', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3b9c48aa-c904-4f5b-87a5-f4dbc23e23a5'	(b) (4), (b) (6) System	12 Aug 2020 02:04:08
User entered 'No (N)'	System	12 Aug 2020 02:04:08

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:57', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3b9c48aa-c904-4f5b-87a5-f4dbc23e23a5'	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Aug 2020 02:04:08

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:03:59', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3b9c48aa-c904-4f5b-87a5-f4dbc23e23a5'	(b) (4), (b) (6) System	12 Aug 2020 02:04:08
User entered 'None (1)'	System	12 Aug 2020 02:04:08

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:02', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3b9c48aa-c904-4f5b-87a5-f4dbc23e23a5'	(b) (4), (b) (6) System	12 Aug 2020 02:04:08
User entered '11 Aug 2020 22:04'	System	12 Aug 2020 02:04:08

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 7'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:22', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '14941d14-a642-4cac-a9da-9d9f4ec91385'	(b) (4), (b) (6)	
	System	13 Aug 2020 05:27:38
User entered 'None (1)'	System	13 Aug 2020 05:27:38

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:25', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '14941d14-a642-4cac-a9da-9d9f4ec91385'	(b) (4), (b) (6)	
User entered 'No (N)'	System	13 Aug 2020 05:27:38

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:27', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '14941d14-a642-4cac-a9da-9d9f4ec91385'	(b) (4), (b) (6) System	13 Aug 2020 05:27:38
User entered 'No (N)'	System	13 Aug 2020 05:27:38

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:30', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '14941d14-a642-4cac-a9da-9d9f4ec91385'	(b) (4), (b) (6)	
	System	13 Aug 2020 05:27:38
User entered 'None (1)'	System	13 Aug 2020 05:27:38

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:33', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '14941d14-a642-4cac-a9da-9d9f4ec91385'	(b) (4), (b) (6) System	13 Aug 2020 05:27:38
User entered '13 Aug 2020 01:27'	System	13 Aug 2020 05:27:38

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:58:06', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0127dd10-b55f-458b-a4e9-42fbeb847999'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Aug 2020 20:58:39

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:58:11', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0127dd10-b55f-458b-a4e9-42fbeb847999'	(b) (4), (b) (6) System	06 Aug 2020 20:58:39
User entered 'None (0)'	System	06 Aug 2020 20:58:39

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:58:15', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0127dd10-b55f-458b-a4e9-42fbeb847999'	(b) (4), (b) (6) System	06 Aug 2020 20:58:39
User entered 'None (0)'	System	06 Aug 2020 20:58:39

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:58:18', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0127dd10-b55f-458b-a4e9-42fbeb847999'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Aug 2020 20:58:39

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:58:20', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0127dd10-b55f-458b-a4e9-42fbeb847999'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Aug 2020 20:58:39

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:58:23', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0127dd10-b55f-458b-a4e9-42fbeb847999'	(b) (4), (b) (6) System	06 Aug 2020 20:58:39
User entered 'None (0)'	System	06 Aug 2020 20:58:39

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:58:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0127dd10-b55f-458b-a4e9-42fbeb847999'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Aug 2020 20:58:39

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-06T16:58:33', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0127dd10-b55f-458b-a4e9-42fbeb847999'	(b) (4), (b) (6) System	06 Aug 2020 20:58:39
User entered '06 Aug 2020 16:58'	System	06 Aug 2020 20:58:39

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '06 Aug 2020 16:43'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '06 Aug 2020 19:13'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:54', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '046667e3-21af-4d36-ae3d-0ef0c2605cae'	(b) (4), (b) (6) System	07 Aug 2020 04:01:13
User entered 'None (0)'	System	07 Aug 2020 04:01:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:56', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '046667e3-21af-4d36-ae3d-0ef0c2605cae'	(b) (4), (b) (6) System	07 Aug 2020 04:01:13
User entered 'None (0)'	System	07 Aug 2020 04:01:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:57', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '046667e3-21af-4d36-ae3d-0ef0c2605cae'	(b) (4), (b) (6) System	07 Aug 2020 04:01:13
User entered 'None (0)'	System	07 Aug 2020 04:01:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:00:59', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '046667e3-21af-4d36-ae3d-0ef0c2605cae'	(b) (4), (b) (6) System	07 Aug 2020 04:01:13
User entered 'None (0)'	System	07 Aug 2020 04:01:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:01:00', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '046667e3-21af-4d36-ae3d-0ef0c2605cae'	(b) (4), (b) (6) System	07 Aug 2020 04:01:13
User entered 'None (0)'	System	07 Aug 2020 04:01:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:01:01', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '046667e3-21af-4d36-ae3d-0ef0c2605cae'	(b) (4), (b) (6) System	07 Aug 2020 04:01:13
User entered 'None (0)'	System	07 Aug 2020 04:01:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:01:03', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '046667e3-21af-4d36-ae3d-0ef0c2605cae'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Aug 2020 04:01:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-07T00:01:06', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '046667e3-21af-4d36-ae3d-0ef0c2605cae'	(b) (4), (b) (6) System	07 Aug 2020 04:01:13
User entered '07 Aug 2020 00:01'	System	07 Aug 2020 04:01:13

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '06 Aug 2020 20:08'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 2'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:36:59', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6d0249d-52c3-48b5-a67b-108528a9997e'	(b) (4), (b) (6)	
User entered 'None (0)'	System	08 Aug 2020 13:37:20

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:37:01', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6d0249d-52c3-48b5-a67b-108528a9997e'	(b) (4), (b) (6)	
User entered 'None (0)'	System	08 Aug 2020 13:37:20

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:37:03', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6d0249d-52c3-48b5-a67b-108528a9997e'	(b) (4), (b) (6)	
User entered 'None (0)'	System	08 Aug 2020 13:37:20

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:37:04', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6d0249d-52c3-48b5-a67b-108528a9997e'	(b) (4), (b) (6) System	08 Aug 2020 13:37:20
User entered 'None (0)'	System	08 Aug 2020 13:37:20

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:37:06', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6d0249d-52c3-48b5-a67b-108528a9997e'	(b) (4), (b) (6) System	08 Aug 2020 13:37:20
User entered 'None (0)'	System	08 Aug 2020 13:37:20

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:37:08', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6d0249d-52c3-48b5-a67b-108528a9997e'	(b) (4), (b) (6) System	08 Aug 2020 13:37:20
User entered 'None (0)'	System	08 Aug 2020 13:37:20

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:37:11', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6d0249d-52c3-48b5-a67b-108528a9997e'	(b) (4), (b) (6) System	08 Aug 2020 13:37:20
User entered 'No (N)'	System	08 Aug 2020 13:37:20

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T09:37:14', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6d0249d-52c3-48b5-a67b-108528a9997e'	(b) (4), (b) (6) System	08 Aug 2020 13:37:20
User entered '08 Aug 2020 09:37'	System	08 Aug 2020 13:37:20

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '07 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 3'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:41', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b59fc7e0-8404-47a0-af1d-a238619337ec'	(b) (4), (b) (6) System	09 Aug 2020 02:08:57
User entered 'None (0)'	System	09 Aug 2020 02:08:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:42', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b59fc7e0-8404-47a0-af1d-a238619337ec'	(b) (4), (b) (6) System	09 Aug 2020 02:08:57
User entered 'None (0)'	System	09 Aug 2020 02:08:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:45', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b59fc7e0-8404-47a0-af1d-a238619337ec'	(b) (4), (b) (6) System	09 Aug 2020 02:08:57
User entered 'None (0)'	System	09 Aug 2020 02:08:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:46', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b59fc7e0-8404-47a0-af1d-a238619337ec'	(b) (4), (b) (6) System	09 Aug 2020 02:08:57
User entered 'None (0)'	System	09 Aug 2020 02:08:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:48', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b59fc7e0-8404-47a0-af1d-a238619337ec'	(b) (4), (b) (6) System	09 Aug 2020 02:08:57
User entered 'None (0)'	System	09 Aug 2020 02:08:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:49', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b59fc7e0-8404-47a0-af1d-a238619337ec'	(b) (4), (b) (6) System	09 Aug 2020 02:08:57
User entered 'None (0)'	System	09 Aug 2020 02:08:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:51', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b59fc7e0-8404-47a0-af1d-a238619337ec'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Aug 2020 02:08:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-08T22:08:55', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b59fc7e0-8404-47a0-af1d-a238619337ec'	(b) (4), (b) (6) System	09 Aug 2020 02:08:57
User entered '08 Aug 2020 22:08'	System	09 Aug 2020 02:08:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 4'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:23', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c942e752-bb3d-46fb-b165-a7e7d16ab985'	(b) (4), (b) (6) System	10 Aug 2020 02:12:57
User entered 'None (0)'	System	10 Aug 2020 02:12:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:27', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c942e752-bb3d-46fb-b165-a7e7d16ab985'	(b) (4), (b) (6) System	10 Aug 2020 02:12:57
User entered 'None (0)'	System	10 Aug 2020 02:12:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:29', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c942e752-bb3d-46fb-b165-a7e7d16ab985'	(b) (4), (b) (6) System	10 Aug 2020 02:12:57
User entered 'None (0)'	System	10 Aug 2020 02:12:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:40', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c942e752-bb3d-46fb-b165-a7e7d16ab985'	(b) (4), (b) (6) System	10 Aug 2020 02:12:57
User entered 'None (0)'	System	10 Aug 2020 02:12:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:44', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c942e752-bb3d-46fb-b165-a7e7d16ab985'	(b) (4), (b) (6) System	10 Aug 2020 02:12:57
User entered 'None (0)'	System	10 Aug 2020 02:12:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:46', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c942e752-bb3d-46fb-b165-a7e7d16ab985'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Aug 2020 02:12:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:49', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c942e752-bb3d-46fb-b165-a7e7d16ab985'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Aug 2020 02:12:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-09T22:12:52', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c942e752-bb3d-46fb-b165-a7e7d16ab985'	(b) (4), (b) (6) System	10 Aug 2020 02:12:57
User entered '09 Aug 2020 22:12'	System	10 Aug 2020 02:12:57

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 5'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:21:56', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8f64b79b-e22d-47a7-b354-423ca7596dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:22:29
User entered 'No interference with activity (1)'	System	11 Aug 2020 00:22:29

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:22:00', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8f64b79b-e22d-47a7-b354-423ca7596dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:22:29
User entered 'Some interference with activity (2)'	System	11 Aug 2020 00:22:29

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:22:04', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8f64b79b-e22d-47a7-b354-423ca7596dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:22:29
User entered 'Some interference with activity (2)'	System	11 Aug 2020 00:22:29

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:22:09', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8f64b79b-e22d-47a7-b354-423ca7596dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:22:29
User entered 'Some interference with activity (2)'	System	11 Aug 2020 00:22:29

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:22:12', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8f64b79b-e22d-47a7-b354-423ca7596dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:22:29
User entered 'None (0)'	System	11 Aug 2020 00:22:29

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:22:18', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8f64b79b-e22d-47a7-b354-423ca7596dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:22:29
User entered 'No interference with activity (1)'	System	11 Aug 2020 00:22:29

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:22:22', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8f64b79b-e22d-47a7-b354-423ca7596dfa'	(b) (4), (b) (6)	
	System	11 Aug 2020 00:22:29
User entered 'No (N)'	System	11 Aug 2020 00:22:29

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-10T20:22:25', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8f64b79b-e22d-47a7-b354-423ca7596dfa'	(b) (4), (b) (6) System	11 Aug 2020 00:22:29
User entered '10 Aug 2020 20:22'	System	11 Aug 2020 00:22:29

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 6'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:07', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c56cdbd5-9a4c-45a4-8ca4-3ef69bdfc55b'	(b) (4), (b) (6) System	12 Aug 2020 02:04:45
User entered 'None (0)'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:16', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c56cbbd5-9a4c-45a4-8ca4-3ef69bdfc55b'	(b) (4), (b) (6) System	12 Aug 2020 02:04:45
User entered 'Some interference with activity (2)'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:22', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c56cdbc5-9a4c-45a4-8ca4-3ef69bdfe55b'	(b) (4), (b) (6)	
	System	12 Aug 2020 02:04:45
User entered 'No interference with activity (1)'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:25', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c56cbbd5-9a4c-45a4-8ca4-3ef69bdfc55b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c56cdbd5-9a4c-45a4-8ca4-3ef69bdfc55b'	(b) (4), (b) (6) System	12 Aug 2020 02:04:45
User entered 'None (0)'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:30', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c56cbbd5-9a4c-45a4-8ca4-3ef69bdfc55b'	(b) (4), (b) (6) System	12 Aug 2020 02:04:45
User entered 'None (0)'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:35', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c56cbbd5-9a4c-45a4-8ca4-3ef69bdfc55b'	(b) (4), (b) (6) System	12 Aug 2020 02:04:45
User entered 'No (N)'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-11T22:04:39', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c56cbbd5-9a4c-45a4-8ca4-3ef69bdfc55b'	(b) (4), (b) (6) System	12 Aug 2020 02:04:45
User entered '11 Aug 2020 22:04'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 7'	System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:38', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '813f467b-6de6-4679-9e59-1078a9f04f59'	(b) (4), (b) (6)	
	System	13 Aug 2020 05:28:22
User entered 'None (0)'	System	13 Aug 2020 05:28:22

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:46', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '813f467b-6de6-4679-9e59-1078a9f04f59'	(b) (4), (b) (6) System	13 Aug 2020 05:28:22
User entered 'No interference with activity (1)'	System	13 Aug 2020 05:28:22

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:49', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '813f467b-6de6-4679-9e59-1078a9f04f59'	(b) (4), (b) (6) System	13 Aug 2020 05:28:22
User entered 'None (0)'	System	13 Aug 2020 05:28:22

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:27:51', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '813f467b-6de6-4679-9e59-1078a9f04f59'	(b) (4), (b) (6)	
	System	13 Aug 2020 05:28:22
User entered 'None (0)'	System	13 Aug 2020 05:28:22

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:28:01', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '813f467b-6de6-4679-9e59-1078a9f04f59'	(b) (4), (b) (6)	
	System	13 Aug 2020 05:28:22
User entered 'None (0)'	System	13 Aug 2020 05:28:22

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:28:05', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '813f467b-6de6-4679-9e59-1078a9f04f59'	(b) (4), (b) (6) System	13 Aug 2020 05:28:22
User entered 'None (0)'	System	13 Aug 2020 05:28:22

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

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 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:28:12', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '813f467b-6de6-4679-9e59-1078a9f04f59'	(b) (4), (b) (6)	
	System	13 Aug 2020 05:28:22
User entered 'No (N)'	System	13 Aug 2020 05:28:22

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T01:28:16', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '813f467b-6de6-4679-9e59-1078a9f04f59'	(b) (4), (b) (6) System	13 Aug 2020 05:28:22
User entered '13 Aug 2020 01:28'	System	13 Aug 2020 05:28:22

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 20:29:33

US3242002

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
	(b) (4), (b) (6)	
Data entry locked.	System	12 Aug 2020 02:04:45
User entered 'Day 8'	System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T21:25:41', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'e5dfeed0-c2cb-479c-8306-1834b98b0941'	(b) (4), (b) (6) System	14 Aug 2020 01:25:50
User entered 'None (0)'	System	14 Aug 2020 01:25:50

US3242002

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T21:25:44', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'e5dfeed0-c2cb-479c-8306-1834b98b0941'	(b) (4), (b) (6) System	14 Aug 2020 01:25:50
User entered '13 Aug 2020 21:25'	System	14 Aug 2020 01:25:50

US3242002

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '13 Aug 2020 12:00'	(b) (4), (b) (6) System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:41:11
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	12 Aug 2020 02:04:45

US3242002

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	12 Aug 2020 02:03:56
User entered 'Day 8'	System	12 Aug 2020 02:03:56

US3242002

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:06:10

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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T21:25:51', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3f4a694f-ba18-4d1f-83cc-4e5999b16e97'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	14 Aug 2020 01:26:01

US3242002

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-08-13T21:25:56', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3f4a694f-ba18-4d1f-83cc-4e5999b16e97'	(b) (4), (b) (6) System	14 Aug 2020 01:26:01
User entered '13 Aug 2020 21:25'	System	14 Aug 2020 01:26:01

US3242002

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '13 Aug 2020 12:00'	(b) (4), (b) (6) System	12 Aug 2020 02:03:56

US3242002

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	12 Aug 2020 02:03:56

US3242002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Aug 2020 14:31:12
	(b) (4)	

US3242002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:21
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 12AUG2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:19:50
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 12AUG2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' answered with 'dcf submitted' (Site from DM).	Donna Toepfer (b) (4)	26 Oct 2020 13:07:47
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 12AUG2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 12:43:40
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
User entered '14 Aug 2020'	Donna Toepfer (b) (4)	17 Aug 2020 14:31:12

US3242002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	17 Aug 2020 14:31:12
	(b) (4)	

US3242002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:21
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	17 Aug 2020 14:31:12
	(b) (4)	

US3242002

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:47:38
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Aug 2020 14:31:17
	(b) (4)	

US3242002

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'I'	(b) (4), (b) (6) System	17 Aug 2020 14:31:17

US3242002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:35
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	31 Aug 2020 11:49:46
	(b) (4)	

US3242002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:49:26
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Nov 2020 16:05:30
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Nov 2020 16:05:30
User entered '21 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 16:05:30
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Nov 2020 16:03:40
DataPoint Un-verified.	Erynn McKinley (b) (4)	19 Nov 2020 16:03:40
Signature has been broken.	(b) (4) Erynn McKinley (b) (4)	19 Nov 2020 16:03:40
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4) Erynn McKinley (b) (4)	19 Nov 2020 16:03:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:35
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '21 Aug 2020'	Grace Newville (b) (4)	31 Aug 2020 11:49:46
	(b) (4)	

US3242002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:35
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	31 Aug 2020 11:49:46
	(b) (4)	

US3242002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:35
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Grace Newville (b) (4)	31 Aug 2020 11:49:46
	(b) (4)	

US3242002

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:48:05
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	31 Aug 2020 11:49:51
	(b) (4)	

US3242002

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:45:18
User entered 'I'	(b) (4), (b) (6) System	31 Aug 2020 11:49:51

US3242002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:48
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	31 Aug 2020 11:50:02
	(b) (4)	

US3242002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:49:45
DataPoint Un-verified.	Erynn McKinley (b) (4)	19 Nov 2020 16:05:59
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 16:05:59
	(b) (4)	
User entered '29 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 16:05:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:48
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '28 Aug 2020'	Grace Newville (b) (4)	31 Aug 2020 11:50:02
	(b) (4)	

US3242002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:48
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	31 Aug 2020 11:50:02
	(b) (4)	

US3242002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:44:48
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Grace Newville (b) (4)	31 Aug 2020 11:50:02
	(b) (4)	

US3242002

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:48:47
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	31 Aug 2020 11:50:07
	(b) (4)	

US3242002

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:19
User entered '1'	(b) (4), (b) (6) System	31 Aug 2020 11:50:07

US3242002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 16:08:44
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:07:22
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:23:12
	(b) (4)	

US3242002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 16:08:43
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:07:22
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 14:23:12
	(b) (4)	

US3242002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 16:08:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:07:22
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 14:23:12
	(b) (4)	

US3242002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered 'VISIT2'	(b) (4), (b) (6) System	01 Oct 2020 14:23:12

US3242002

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	29 Sep 2020 20:01:17
	(b) (4)	

US3242002

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:40
User entered '1'	(b) (4), (b) (6) System	29 Sep 2020 20:01:17

US3242002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User closed query 'Per CDM: Response noted however this data is required. Kindly review and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:07:44
Query 'Per CDM: Response noted however this data is required. Kindly review and update if appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	29 Oct 2020 13:49:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 13:49:00
	(b) (4)	
User opened query 'Per CDM: Response noted however this data is required. Kindly review and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 21:21:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 21:19:59
Query 'Data is required. Please complete.' answered with 'covid impact' (Site from System).	Donna Toepfer (b) (4)	19 Oct 2020 16:05:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 16:04:52
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	19 Oct 2020 16:04:52
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 16:04:52
	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:59:08
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Oct 2020 15:59:08
	(b) (4)	

US3242002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 15:59:08
	(b) (4)	

US3242002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 16:05:22
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Donna Toepfer (b) (4)	19 Oct 2020 15:59:08
	(b) (4)	

US3242002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User entered 'subject did not get Vaccine 2 and was not contacted for phone calls' reason for change:	Donna Toepfer (b) (4)	29 Oct 2020 13:49:00
	(b) (4)	
Data Entry Error		
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	19 Oct 2020 16:05:22
Please review and reconcile.' (Site from System).		
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	19 Oct 2020 15:59:08
Please review and reconcile.' (Site from System).		
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 15:59:08
	(b) (4)	

US3242002

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User entered 'Yes (Y)'	Grace Newville (b) (4)	29 Sep 2020 20:22:26
	(b) (4)	

US3242002

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered 'I'	(b) (4), (b) (6) System	29 Sep 2020 20:22:26

US3242002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	29 Oct 2020 13:48:28
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	29 Oct 2020 13:48:04
User entered 'No (N)'	Donna Toepfer (b) (4)	29 Oct 2020 13:48:04
	(b) (4)	

US3242002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User entered empty.	Donna Toepfer (b) (4)	29 Oct 2020 13:48:04
	(b) (4)	

US3242002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 13:48:28
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Donna Toepfer (b) (4)	29 Oct 2020 13:48:04
	(b) (4)	

US3242002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User entered 'subject did not get Vaccine 2, so contact was not done'	Donna Toepfer (b) (4)	29 Oct 2020 13:48:04
	(b) (4)	

US3242002

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:11
User entered 'Yes (Y)'	Grace Newville (b) (4)	29 Sep 2020 20:22:33
	(b) (4)	

US3242002

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered 'I'	(b) (4), (b) (6) System	29 Sep 2020 20:22:33

US3242002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'No (N)'	Donna Toepfer (b) (4)	29 Oct 2020 13:49:47
	(b) (4)	

US3242002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered empty.	Donna Toepfer (b) (4)	29 Oct 2020 13:49:47
	(b) (4)	

US3242002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered empty.	Donna Toepfer (b) (4)	29 Oct 2020 13:49:47
	(b) (4)	

US3242002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'subject did not get Vaccine 2 and subject was was contacted for phone calls'	Donna Toepfer (b) (4)	29 Oct 2020 13:49:47
	(b) (4)	

US3242002

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Yes (Y)'	Grace Newville (b) (4)	29 Sep 2020 20:22:39
	(b) (4)	

US3242002

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered '1'	(b) (4), (b) (6) System	29 Sep 2020 20:22:39

US3242002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:00
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered '29 Sep 2020'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:00
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:00
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered 'VISIT3'	(b) (4), (b) (6) System	01 Oct 2020 18:46:00

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '29 Sep 2020'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '15:55'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered '29 Sep 2020 15:55'	(b) (4), (b) (6) System	01 Oct 2020 18:46:38

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '97.1' F	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '90'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered 'bpm'	(b) (4), (b) (6) System	01 Oct 2020 18:46:38

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '20'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered 'breaths/min'	(b) (4), (b) (6) System	01 Oct 2020 18:46:38

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '120'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 18:46:38

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '70'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:38
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 18:46:38

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 07:17:29

US3242002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 07:17:29

US3242002

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 18:46:44
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 18:46:44
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 18:47:00
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered '29 Sep 2020'	Donna Toepfer (b) (4)	01 Oct 2020 18:47:00
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered '16:18'	Donna Toepfer (b) (4)	01 Oct 2020 18:47:00
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered '29 Sep 2020 16:18'	(b) (4), (b) (6) System	01 Oct 2020 18:47:00

US3242002

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Yes (Y)'	Grace Newville (b) (4)	29 Sep 2020 20:22:56
	(b) (4)	

US3242002

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered '1'	(b) (4), (b) (6) System	29 Sep 2020 20:22:56

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 64'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-06T21:28:05', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9b019ea3-3171-46a5-8ba6-1abbc84b5739'	(b) (4), (b) (6) System	07 Oct 2020 01:28:19
User entered 'No (N)'	System	07 Oct 2020 01:28:19

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-06T21:28:09', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9b019ea3-3171-46a5-8ba6-1abbc84b5739'	(b) (4), (b) (6)	
	System	07 Oct 2020 01:28:19
User entered 'No (N)'	System	07 Oct 2020 01:28:19

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-06T21:28:13', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9b019ea3-3171-46a5-8ba6-1abbc84b5739'	(b) (4), (b) (6) System	07 Oct 2020 01:28:19
User entered '06 Oct 2020 21:28:13'	System	07 Oct 2020 01:28:19

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 71'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-15T09:12:11', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1e0f0d65-33cc-4bd9-b73b-3abb43262dc0'	(b) (4), (b) (6)	
	System	15 Oct 2020 13:12:30
User entered 'No (N)'	System	15 Oct 2020 13:12:30

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-15T09:12:20', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1e0f0d65-33cc-4bd9-b73b-3abb43262dc0'	(b) (4), (b) (6)	
	System	15 Oct 2020 13:12:30
User entered 'No (N)'	System	15 Oct 2020 13:12:30

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-15T09:12:24', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1e0f0d65-33cc-4bd9-b73b-3abb43262dc0' User entered '15 Oct 2020 09:12:24'	(b) (4), (b) (6) System	15 Oct 2020 13:12:30
	System	15 Oct 2020 13:12:30

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 78'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-22T20:04:25', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '81f4d63c-4321-4c6c-8bbc-7fcf708ba14b'	(b) (4), (b) (6)	
	System	23 Oct 2020 00:04:38
User entered 'No (N)'	System	23 Oct 2020 00:04:38

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-22T20:04:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '81f4d63c-4321-4c6c-8bbc-7fcf708ba14b'	(b) (4), (b) (6)	
	System	23 Oct 2020 00:04:38
User entered 'No (N)'	System	23 Oct 2020 00:04:38

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-10-22T20:04:32', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '81f4d63c-4321-4c6c-8bbc-7fcf708ba14b'	(b) (4), (b) (6) System	23 Oct 2020 00:04:38
User entered '22 Oct 2020 20:04:32'	System	23 Oct 2020 00:04:38

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 92'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-05T19:26:53', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '08f0b865-4511-47d2-9b31-19148aaa1970'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Nov 2020 00:27:07

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-05T19:26:56', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '08f0b865-4511-47d2-9b31-19148aaa1970'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Nov 2020 00:27:07

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-05T19:27:00', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '08f0b865-4511-47d2-9b31-19148aaa1970'	(b) (4), (b) (6) System	06 Nov 2020 00:27:07
User entered '05 Nov 2020 19:27:00'	System	06 Nov 2020 00:27:07

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 99'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-10T15:28:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '5c4adc40-c246-400f-a384-f79b90baad22'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Nov 2020 20:29:00

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-10T15:28:36', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '5c4adc40-c246-400f-a384-f79b90baad22'	(b) (4), (b) (6)	
	System	10 Nov 2020 20:29:00
User entered 'No (N)'	System	10 Nov 2020 20:29:00

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-10T15:28:56', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '5c4adc40-c246-400f-a384-f79b90baad22' User entered '10 Nov 2020 15:28:56'	(b) (4), (b) (6) System	10 Nov 2020 20:29:00
	System	10 Nov 2020 20:29:00

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered 'Day 106'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-18T11:06:59', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c035f218-83a0-4ac7-a5bb-841594972c1b'	(b) (4), (b) (6)	
	System	18 Nov 2020 16:07:12
User entered 'No (N)'	System	18 Nov 2020 16:07:12

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-18T11:07:02', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c035f218-83a0-4ac7-a5bb-841594972c1b'	(b) (4), (b) (6)	
	System	18 Nov 2020 16:07:12
User entered 'No (N)'	System	18 Nov 2020 16:07:12

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-18T11:07:05', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'c035f218-83a0-4ac7-a5bb-841594972c1b'	(b) (4), (b) (6)	
	System	18 Nov 2020 16:07:12
User entered '18 Nov 2020 11:07:05'	System	18 Nov 2020 16:07:12

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 20:29:33

US3242002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:47:27
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 20:29:33
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 20:29:33

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (3eb396fd3c0e3035)', Time: '2020-11-23T18:24:21', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0ba3aa38-45be-40da-9db4-0844b58bf39'	System	23 Nov 2020 23:24:35
User entered 'No (N)'	System	23 Nov 2020 23:24:35

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (3eb396fd3c0e3035)', Time: '2020-11-23T18:24:23', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0ba3aa38-45be-40da-9db4-0844b58bf39'	System	23 Nov 2020 23:24:35
User entered 'No (N)'	System	23 Nov 2020 23:24:35

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-23T18:24:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '0ba3aa38-45be-40da-9db4-0844b58bf39'	System	23 Nov 2020 23:24:35
User entered '23 Nov 2020 18:24:28'	System	23 Nov 2020 23:24:35

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (3eb396fd3c0e3035)', Time: '2020-11-30T19:58:38', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9116fae7-2b11-48d5-b8b4-c7a81cb26d62'	System	01 Dec 2020 00:58:52
User entered 'No (N)'	System	01 Dec 2020 00:58:52

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Have you been exposed to someone with 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 (3eb396fd3c0e3035)', Time: '2020-11-30T19:58:40', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9116fae7-2b11-48d5-b8b4-c7a81cb26d62'	System	01 Dec 2020 00:58:52
User entered 'No (N)'	System	01 Dec 2020 00:58:52

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-11-30T19:58:44', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '9116fae7-2b11-48d5-b8b4-c7a81cb26d62'	System	01 Dec 2020 00:58:52
User entered '30 Nov 2020 19:58:44'	System	01 Dec 2020 00:58:52

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (3eb396fd3c0e3035)', Time: '2020-12-08T09:19:24', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b989ce8a-7749-4be6-9fce-24cc9ba117f0'	System	08 Dec 2020 14:19:34
User entered 'No (N)'	System	08 Dec 2020 14:19:34

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (3eb396fd3c0e3035)', Time: '2020-12-08T09:19:26', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b989ce8a-7749-4be6-9fce-24cc9ba117f0'	System	08 Dec 2020 14:19:34
User entered 'No (N)'	System	08 Dec 2020 14:19:34

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-12-08T09:19:29', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'b989ce8a-7749-4be6-9fce-24cc9ba117f0'	System	08 Dec 2020 14:19:34
User entered '08 Dec 2020 09:19:29'	System	08 Dec 2020 14:19:34

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (3eb396fd3c0e3035)', Time: '2020-12-15T09:19:00', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6888bcf-6dae-4588-ac63-66ddcc2cf73c'	System	15 Dec 2020 14:19:11
User entered 'No (N)'	System	15 Dec 2020 14:19:11

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (3eb396fd3c0e3035)', Time: '2020-12-15T09:19:02', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6888bcf-6dae-4588-ac63-66ddcc2cf73c'	System	15 Dec 2020 14:19:11
User entered 'No (N)'	System	15 Dec 2020 14:19:11

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-12-15T09:19:07', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f6888bcf-6dae-4588-ac63-66ddcc2cf73c'	System	15 Dec 2020 14:19:11
User entered '15 Dec 2020 09:19:07'	System	15 Dec 2020 14:19:11

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (3eb396fd3c0e3035)', Time: '2020-12-21T15:39:02', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3f52aeb0-fe1e-4180-aeda-17f682186411'	System	21 Dec 2020 20:39:17
User entered 'No (N)'	System	21 Dec 2020 20:39:17

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (3eb396fd3c0e3035)', Time: '2020-12-21T15:39:04', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3f52aeb0-fe1e-4180-aeda-17f682186411'	System	21 Dec 2020 20:39:17
User entered 'No (N)'	System	21 Dec 2020 20:39:17

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-12-21T15:39:08', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '3f52aeb0-fe1e-4180-aeda-17f682186411'	System	21 Dec 2020 20:39:17
User entered '21 Dec 2020 15:39:08'	System	21 Dec 2020 20:39:17

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (3eb396fd3c0e3035)', Time: '2020-12-29T13:40:23', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '7c0d810b-d312-44e2-8c02-aa7b6d8119c6'	System	29 Dec 2020 18:40:37
User entered 'No (N)'	System	29 Dec 2020 18:40:37

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Have you been exposed to someone with 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 (3eb396fd3c0e3035)', Time: '2020-12-29T13:40:27', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '7c0d810b-d312-44e2-8c02-aa7b6d8119c6'	System	29 Dec 2020 18:40:37
User entered 'No (N)'	System	29 Dec 2020 18:40:37

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2020-12-29T13:40:32', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '7c0d810b-d312-44e2-8c02-aa7b6d8119c6'	System	29 Dec 2020 18:40:37
User entered '29 Dec 2020 13:40:32'	System	29 Dec 2020 18:40:37

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (3eb396fd3c0e3035)', Time: '2021-01-05T12:23:32', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '66fc9b36-d113-47c9-b422-3cfa233a90bc'	System	05 Jan 2021 17:23:42
User entered 'No (N)'	System	05 Jan 2021 17:23:42

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (3eb396fd3c0e3035)', Time: '2021-01-05T12:23:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '66fc9b36-d113-47c9-b422-3cfa233a90bc'	System	05 Jan 2021 17:23:42
User entered 'No (N)'	System	05 Jan 2021 17:23:42

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2021-01-05T12:23:38', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '66fc9b36-d113-47c9-b422-3cfa233a90bc'	System	05 Jan 2021 17:23:42
User entered '05 Jan 2021 12:23:38'	System	05 Jan 2021 17:23:42

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (3eb396fd3c0e3035)', Time: '2021-01-11T21:58:29', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1a4218c0-e590-4566-a651-894b1a895be5'	System	12 Jan 2021 02:58:41
User entered 'No (N)'	System	12 Jan 2021 02:58:41

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (3eb396fd3c0e3035)', Time: '2021-01-11T21:58:31', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1a4218c0-e590-4566-a651-894b1a895be5'	System	12 Jan 2021 02:58:41
User entered 'No (N)'	System	12 Jan 2021 02:58:41

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb396fd3c0e3035)', Time: '2021-01-11T21:58:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1a4218c0-e590-4566-a651-894b1a895be5'	System	12 Jan 2021 02:58:41
User entered '11 Jan 2021 21:58:34'	System	12 Jan 2021 02:58:41

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-01-20T14:48:43', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a3e9e69e-9ec5-4b60-9a95-ed0d7f2d6399'	System	20 Jan 2021 19:48:54
User entered 'No (N)'	System	20 Jan 2021 19:48:54

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-01-20T14:48:45', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a3e9e69e-9ec5-4b60-9a95-ed0d7f2d6399'	System	20 Jan 2021 19:48:54
User entered 'No (N)'	System	20 Jan 2021 19:48:54

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-01-20T14:48:50', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'a3e9e69e-9ec5-4b60-9a95-ed0d7f2d6399'	System	20 Jan 2021 19:48:54
User entered '20 Jan 2021 14:48:50'	System	20 Jan 2021 19:48:54

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-01-26T18:00:00', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '98df9ae3-9465-4ba4-a237-41ac823b6348'	System	27 Jan 2021 00:38:12
User entered 'No (N)'	System	27 Jan 2021 00:38:12

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-01-26T18:00:02', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '98df9ae3-9465-4ba4-a237-41ac823b6348'	System	27 Jan 2021 00:38:12
User entered 'No (N)'	System	27 Jan 2021 00:38:12

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-01-26T18:00:07', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '98df9ae3-9465-4ba4-a237-41ac823b6348'	System	27 Jan 2021 00:38:12
User entered '26 Jan 2021 18:00:07'	System	27 Jan 2021 00:38:12

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-02-01T21:53:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'bfb11615-afbb-46a3-95d2-a45f522f5216'	System	02 Feb 2021 02:53:42
User entered 'No (N)'	System	02 Feb 2021 02:53:42

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-02-01T21:53:36', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'bfb11615-afbb-46a3-95d2-a45f522f5216'	System	02 Feb 2021 02:53:42
User entered 'No (N)'	System	02 Feb 2021 02:53:42

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-02-01T21:53:40', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'bfb11615-afbb-46a3-95d2-a45f522f5216'	System	02 Feb 2021 02:53:42
User entered '01 Feb 2021 21:53:40'	System	02 Feb 2021 02:53:42

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-02-08T16:41:22', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1e592c3d-5ebb-45b1-90a1-b2a53ccf158c'	System	08 Feb 2021 21:41:34
User entered 'No (N)'	System	08 Feb 2021 21:41:34

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-02-08T16:41:25', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1e592c3d-5ebb-45b1-90a1-b2a53ccf158c'	System	08 Feb 2021 21:41:34
User entered 'No (N)'	System	08 Feb 2021 21:41:34

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-02-08T16:41:29', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '1e592c3d-5ebb-45b1-90a1-b2a53ccf158c'	System	08 Feb 2021 21:41:34
User entered '08 Feb 2021 16:41:29'	System	08 Feb 2021 21:41:34

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-02-14T20:33:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8abc5a68-443b-4007-a02d-fceb6092f2c2'	System	15 Feb 2021 01:33:52
User entered 'No (N)'	System	15 Feb 2021 01:33:52

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-02-14T20:33:44', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8abc5a68-443b-4007-a02d-fceb6092f2c2'	System	15 Feb 2021 01:33:52
User entered 'No (N)'	System	15 Feb 2021 01:33:52

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-02-14T20:33:47', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8abc5a68-443b-4007-a02d-fceb6092f2c2'	System	15 Feb 2021 01:33:52
User entered '14 Feb 2021 20:33:47'	System	15 Feb 2021 01:33:52

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-02-24T11:31:13', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '52f7335e-7079-4660-a11a-78bd824feb41'	System	24 Feb 2021 16:31:27
User entered 'No (N)'	System	24 Feb 2021 16:31:27

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-02-24T11:31:16', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '52f7335e-7079-4660-a11a-78bd824feb41'	System	24 Feb 2021 16:31:27
User entered 'No (N)'	System	24 Feb 2021 16:31:27

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-02-24T11:31:21', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '52f7335e-7079-4660-a11a-78bd824feb41'	System	24 Feb 2021 16:31:27
User entered '24 Feb 2021 11:31:21'	System	24 Feb 2021 16:31:27

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-03-03T01:43:00', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8b96c8ad-d9c8-4464-9a9f-64f35c9629e6'	System	03 Mar 2021 06:43:10
User entered 'No (N)'	System	03 Mar 2021 06:43:10

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-03-03T01:43:03', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8b96c8ad-d9c8-4464-9a9f-64f35c9629e6'	System	03 Mar 2021 06:43:10
User entered 'No (N)'	System	03 Mar 2021 06:43:10

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-03-03T01:43:07', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '8b96c8ad-d9c8-4464-9a9f-64f35c9629e6'	System	03 Mar 2021 06:43:10
User entered '03 Mar 2021 01:43:07'	System	03 Mar 2021 06:43:10

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-03-08T17:04:30', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f21a948b-e254-49a7-875b-c185ab37e755'	System	08 Mar 2021 22:04:36
User entered 'No (N)'	System	08 Mar 2021 22:04:36

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-03-08T17:04:31', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f21a948b-e254-49a7-875b-c185ab37e755'	System	08 Mar 2021 22:04:36
User entered 'No (N)'	System	08 Mar 2021 22:04:36

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-03-08T17:04:34', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f21a948b-e254-49a7-875b-c185ab37e755'	System	08 Mar 2021 22:04:36
User entered '08 Mar 2021 17:04:34'	System	08 Mar 2021 22:04:36

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-03-17T10:20:49', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '325ff605-2ec3-419d-8263-8954e7f8d844'	System	17 Mar 2021 14:20:58
User entered 'No (N)'	System	17 Mar 2021 14:20:58

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-03-17T10:20:52', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '325ff605-2ec3-419d-8263-8954e7f8d844'	System	17 Mar 2021 14:20:58
User entered 'No (N)'	System	17 Mar 2021 14:20:58

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-03-17T10:20:54', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '325ff605-2ec3-419d-8263-8954e7f8d844'	System	17 Mar 2021 14:20:58
User entered '17 Mar 2021 10:20:54'	System	17 Mar 2021 14:20:58

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-03-24T17:16:25', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '72d84a51-1c88-4826-a4c2-ad673dc7c3f6'	System	24 Mar 2021 21:16:38
User entered 'No (N)'	System	24 Mar 2021 21:16:38

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-03-24T17:16:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '72d84a51-1c88-4826-a4c2-ad673dc7c3f6'	System	24 Mar 2021 21:16:38
User entered 'No (N)'	System	24 Mar 2021 21:16:38

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-03-24T17:16:33', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '72d84a51-1c88-4826-a4c2-ad673dc7c3f6'	System	24 Mar 2021 21:16:38
User entered '24 Mar 2021 17:16:33'	System	24 Mar 2021 21:16:38

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-03-31T21:50:33', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '215ff33c-ab9b-484b-8f43-711a9b23c8b1'	System	01 Apr 2021 01:50:41
User entered 'No (N)'	System	01 Apr 2021 01:50:41

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-03-31T21:50:35', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '215ff33c-ab9b-484b-8f43-711a9b23c8b1'	System	01 Apr 2021 01:50:41
User entered 'No (N)'	System	01 Apr 2021 01:50:41

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-03-31T21:50:38', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '215ff33c-ab9b-484b-8f43-711a9b23c8b1'	System	01 Apr 2021 01:50:41
User entered '31 Mar 2021 21:50:38'	System	01 Apr 2021 01:50:41

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-04-05T16:56:37', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '961bfd53-9447-406f-88e1-d45068fcd936'	System	05 Apr 2021 20:56:48
User entered 'No (N)'	System	05 Apr 2021 20:56:48

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-04-05T16:56:39', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '961bfd53-9447-406f-88e1-d45068fcd936'	System	05 Apr 2021 20:56:48
User entered 'No (N)'	System	05 Apr 2021 20:56:48

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-04-05T16:56:42', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '961bfd53-9447-406f-88e1-d45068fcd936'	System	05 Apr 2021 20:56:48
User entered '05 Apr 2021 16:56:42'	System	05 Apr 2021 20:56:48

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-04-14T21:37:48', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '338c697b-6f34-47c1-9143-e3c6158885ff'	System	15 Apr 2021 01:38:03
User entered 'No (N)'	System	15 Apr 2021 01:38:03

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-04-14T21:37:50', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '338c697b-6f34-47c1-9143-e3c6158885ff'	System	15 Apr 2021 01:38:03
User entered 'No (N)'	System	15 Apr 2021 01:38:03

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-04-14T21:37:54', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '338c697b-6f34-47c1-9143-e3c6158885ff' User entered '14 Apr 2021 21:37:54'	System	15 Apr 2021 01:38:03

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-04-20T08:44:18', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f3fccabb-0347-45bc-9ddb-c09ffedc8a70'	System	20 Apr 2021 12:44:33
User entered 'No (N)'	System	20 Apr 2021 12:44:33

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-04-20T08:44:24', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f3fccabb-0347-45bc-9ddb-c09ffedc8a70'	System	20 Apr 2021 12:44:33
User entered 'No (N)'	System	20 Apr 2021 12:44:33

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-04-20T08:44:28', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'f3fccabb-0347-45bc-9ddb-c09ffedc8a70'	System	20 Apr 2021 12:44:33
User entered '20 Apr 2021 08:44:28'	System	20 Apr 2021 12:44:33

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[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 (481895287482c9a0)', Time: '2021-04-26T16:56:41', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'cb2aaec5-6289-4d77-8be0-cffefa554bd5'	System	26 Apr 2021 20:56:53
User entered 'No (N)'	System	26 Apr 2021 20:56:53

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

Have you been exposed to someone with 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 (481895287482c9a0)', Time: '2021-04-26T16:56:44', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'cb2aaec5-6289-4d77-8be0-cffefa554bd5'	System	26 Apr 2021 20:56:53
User entered 'No (N)'	System	26 Apr 2021 20:56:53

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-04-26T16:56:47', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: 'cb2aaec5-6289-4d77-8be0-cffefa554bd5'	System	26 Apr 2021 20:56:53
User entered '26 Apr 2021 16:56:47'	System	26 Apr 2021 20:56:53

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:13:19

US3242002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:13:19
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:13:19

US3242002

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:06:10

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 11:13:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-03-03T01:43:16', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '58575b8c-927f-4cad-8cea-b1dd1b6e2b41'	(b) (4), (b) (6)	
	System	03 Mar 2021 06:43:23
User entered 'No (N)'	System	03 Mar 2021 06:43:23

US3242002

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:06:10

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:13:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (481895287482c9a0)', Time: '2021-03-03T01:43:20', User OID: 'PatientReportedOutcome (US3242002)', ODM File OID: '58575b8c-927f-4cad-8cea-b1dd1b6e2b41'	(b) (4), (b) (6)	
	System	03 Mar 2021 06:43:23
User entered '03 Mar 2021 01:43:20'	System	03 Mar 2021 06:43:23

US3242002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Nov 2020 21:43:42
	(b) (4)	

US3242002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered '2 Nov 2020'	Erynn McKinley (b) (4)	10 Nov 2020 21:43:42
	(b) (4)	

US3242002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	10 Nov 2020 21:43:42
	(b) (4)	

US3242002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 21:43:42
	(b) (4)	

US3242002

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:43:21
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Nov 2020 21:43:45
	(b) (4)	

US3242002

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:17:29
User entered 'I'	(b) (4), (b) (6) System	10 Nov 2020 21:43:45

US3242002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Dec 2020 21:40:36
	(b) (4)	

US3242002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '1 Dec 2020'	Erynn McKinley (b) (4)	30 Dec 2020 21:40:36
	(b) (4)	

US3242002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	30 Dec 2020 21:40:36
	(b) (4)	

US3242002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Dec 2020 21:40:36
	(b) (4)	

US3242002

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Dec 2020 21:40:39
	(b) (4)	

US3242002

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered '1'	(b) (4), (b) (6) System	30 Dec 2020 21:40:39

US3242002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Dec 2020 21:40:56
	(b) (4)	

US3242002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '30 Dec 2020'	Erynn McKinley (b) (4)	30 Dec 2020 21:40:56
	(b) (4)	

US3242002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	30 Dec 2020 21:40:56

US3242002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Dec 2020 21:40:56
	(b) (4)	

US3242002

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Dec 2020 21:40:59
	(b) (4)	

US3242002

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered '1'	(b) (4), (b) (6) System	30 Dec 2020 21:40:59

US3242002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	01 Feb 2021 21:18:28
	(b) (4)	

US3242002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '29 Jan 2021'	Erynn McKinley (b) (4)	01 Feb 2021 21:18:28
	(b) (4)	

US3242002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	01 Feb 2021 21:18:28
	(b) (4)	

US3242002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	01 Feb 2021 21:18:28
	(b) (4)	

US3242002

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	01 Feb 2021 21:18:33
	(b) (4)	

US3242002

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered '1'	(b) (4), (b) (6) System	01 Feb 2021 21:18:33

US3242002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Mar 2021 21:46:58
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered '08 Mar 2021'	Erynn McKinley (b) (4)	08 Mar 2021 21:46:58
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	08 Mar 2021 21:46:58
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered 'VISIT4'	(b) (4), (b) (6) System	08 Mar 2021 21:46:58

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:37:44
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:37:44
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:37:44
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:37:44
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:57:10
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:37:44
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:57:10
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:37:44
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:37:44
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:37:44
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:37:44
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:37:44
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:57:10

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07

US3242002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07

US3242002

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered 'No (N)'	Erynn McKinley (b) (4)	08 Mar 2021 21:47:04
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	08 Mar 2021 21:47:04
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:47:19

US3242002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered '08 Mar 2021'	Erynn McKinley (b) (4)	08 Mar 2021 21:47:19
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered '16:35'	Erynn McKinley (b) (4)	08 Mar 2021 21:47:19
	(b) (4)	

US3242002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered '08 Mar 2021 16:35'	(b) (4), (b) (6) System	08 Mar 2021 21:47:19

US3242002

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:57:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:47:23

US3242002

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:57:07
User entered '1'	(b) (4), (b) (6) System	08 Mar 2021 21:47:23

US3242002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	30 Mar 2021 14:41:40
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	29 Mar 2021 21:16:17

US3242002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:57
User signature succeeded.	Nathan Segall (b) (4)	30 Mar 2021 14:41:40
	(b) (4)	
User entered '29 Mar 2021'	Erynn McKinley (b) (4)	29 Mar 2021 21:16:17
	(b) (4)	

US3242002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	30 Mar 2021 14:41:40
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	29 Mar 2021 21:16:17

US3242002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	30 Mar 2021 14:41:40
User entered empty.	Erynn McKinley (b) (4) (b) (4)	29 Mar 2021 21:16:17

US3242002

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	30 Mar 2021 14:41:40
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	29 Mar 2021 21:16:19

US3242002

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:57
User entered 'I'	System	29 Mar 2021 21:16:19

US3242002

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	28 Apr 2021 22:08:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 15:37:13

US3242002

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	28 Apr 2021 22:08:50
User entered '28 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 15:37:13

US3242002

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	28 Apr 2021 22:08:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Apr 2021 15:37:13

US3242002

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	28 Apr 2021 22:08:50
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:37:13

US3242002

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	28 Apr 2021 22:08:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 15:37:19

US3242002

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 15:37:19

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:27
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12AUG2020 is reported under Illness visit 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)	17 Nov 2020 14:32:48
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12AUG2020 is reported under Illness visit 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 'Saliva Collection started on 14Aug2020' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	06 Nov 2020 13:11:03
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12AUG2020 is reported under Illness visit 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)	06 Nov 2020 08:50:17
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:29
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '10 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:48:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:27
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:29
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '22:05'	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:48:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:27
User entered '10 Aug 2020 22:05'	System	11 Aug 2020 14:48:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:27
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:29
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Safety Call (Safety Call)'	Donna Toepfer (b) (4)	11 Aug 2020 14:48:00
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:27
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:29
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:48:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 1 (Day 1)'	Donna Toepfer (b) (4)	17 Aug 2020 14:34:29
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '09 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:07:17
User closed query 'Per ETRTR: According to Preclarus Lab Portal, please add Illness visit dated 12Aug20, thanks.' (Site from CRA). Signature has been broken.	(b) (4), (b) (6) Donna Toepfer (b) (4) (b) (4)	14 Sep 2020 14:08:07 10 Sep 2020 16:00:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
Query 'Per ETRTR: According to Preclarus Lab Portal, please add Illness visit dated 12Aug20, thanks.' answered with 'per source phone contact and dairy, start date was 09 Aug 2020' (Site from CRA). User opened query 'Per ETRTR: According to Preclarus Lab Portal, please add Illness visit dated 12Aug20, thanks.' (Site from CRA).	Donna Toepfer (b) (4) (b) (4) (b) (4), (b) (6)	24 Aug 2020 21:08:21 24 Aug 2020 14:35:05
User entered '12 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	19 Aug 2020 23:56:08
User entered '13 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 21:04:31
User entered '12 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23
User entered '13 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Query 'Per CDM: Thanks for your response however, data field concerned has not been updated as per the previous query.' canceled (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:57:04
User opened query 'Per CDM: Thanks for your response however, data field concerned has not been updated as per the previous query.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:55:04
User closed query 'Per CDM: It appears data is missing from several data fields within the entire Symptom Log for Day 1. If not collected, please consider recording those as Not Done ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:55:04
Query 'Per CDM: It appears data is missing from several data fields within the entire Symptom Log for Day 1. If not collected, please consider recording those as Not Done ' answered with 'update' (Site from DM).	Donna Toepfer (b) (4)	07 Jan 2021 21:09:58
	(b) (4)	
User opened query 'Per CDM: It appears data is missing from several data fields within the entire Symptom Log for Day 1. If not collected, please consider recording those as Not Done ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:27:47
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 16:11:01
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	17 Aug 2020 14:34:29
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:24:56
User closed query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-3 and Temperature for Days 1. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:54:07
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	07 Jan 2021 21:10:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	07 Jan 2021 21:10:57
Query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-3 and Temperature for Days 1. If not collected, please consider recording these as NOT DONE' answered with 'update' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	07 Jan 2021 21:10:04
User opened query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-3 and Temperature for Days 1. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:27:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:07:17
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:07:17
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	19 Aug 2020 23:56:08

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 21:04:31
User entered '95' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered '100'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	07 Jan 2021 21:10:57
User entered empty.	System	18 Sep 2020 15:07:17
User entered '%'	System	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:24:56
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:10:57
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:10:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:07:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:07:17
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '100.3' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Aug 2020 23:56:08
	(b) (4)	
User entered '99.7' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Aug 2020 21:04:31
	(b) (4)	
User entered '99.4' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Aug 2020 14:35:23
	(b) (4)	
User entered '99.7' F	Donna Toepfer (b) (4)	17 Aug 2020 14:34:29
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:24:56
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:10:57
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:10:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:07:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:07:17
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Aug 2020 23:56:08
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	17 Aug 2020 14:34:29
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:07:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:07:17
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	19 Aug 2020 23:56:08
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:07:17
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:07:17
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Aug 2020 23:56:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Aug 2020 21:04:31
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Aug 2020 14:35:23
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	17 Aug 2020 14:34:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:07:17
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:07:17
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Aug 2020 23:56:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Aug 2020 21:04:31
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Aug 2020 14:35:23
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	17 Aug 2020 14:34:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:07:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:07:17
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:34:29

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 2 (Day 2)' reason for change:	Donna Toepfer (b) (4)	17 Aug 2020 14:37:25
Data Entry Error	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	17 Aug 2020 14:35:23
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:08:27
	(b) (4)	
User entered '10 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:08:27
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '13 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Aug 2020 23:57:12
	(b) (4)	
User entered '14 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Aug 2020 23:00:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:37:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:37:25
User entered '13 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Aug 2020 14:37:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:35:23
User entered empty.	Donna Toepfer (b) (4)	17 Aug 2020 14:35:23
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:24:56
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:11:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:08:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:08:27
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '100' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Aug 2020 14:37:25
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	17 Aug 2020 14:35:23
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	07 Jan 2021 21:11:26
User entered empty.	System	18 Sep 2020 15:08:27
User entered '%'	System	17 Aug 2020 14:37:25
User entered empty.	System	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:08:27
User entered '100.4' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:08:27
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99.7' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:08:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:08:27
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:08:27
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:08:27
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	19 Aug 2020 23:57:12
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:08:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:08:27
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Aug 2020 14:37:25
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	17 Aug 2020 14:35:23
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:37:25
User entered empty.	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:35:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 3 (Day 3)' reason for change:	Donna Toepfer (b) (4)	18 Aug 2020 23:00:02
Data Entry Error	(b) (4)	
User entered 'Day 4 (Day 4)'	Donna Toepfer (b) (4)	17 Aug 2020 14:39:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:10:01
	(b) (4)	
User entered '11 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:10:01
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '14 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Aug 2020 23:57:47
	(b) (4)	
User entered '15 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Aug 2020 23:00:02
	(b) (4)	
User entered '14 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Aug 2020 21:02:18
	(b) (4)	
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	17 Aug 2020 14:39:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:24:56
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	07 Jan 2021 21:11:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	07 Jan 2021 21:11:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:10:01
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:10:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	07 Jan 2021 21:11:37
User entered empty.	System	18 Sep 2020 15:10:01
User entered '%'	System	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:10:01
	(b) (4)	
User entered '99.1' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:10:01
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '98.3' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Aug 2020 21:02:18
	(b) (4)	
User entered '99.4' F	Donna Toepfer (b) (4)	17 Aug 2020 14:39:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:10:01
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:10:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:10:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:10:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	17 Aug 2020 14:39:14

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 4 (Day 4)'	Donna Toepfer (b) (4)	18 Aug 2020 23:00:02
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User entered '12 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '15 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:07:25
User entered '16 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	20 Aug 2020 00:01:44
User entered empty.	System	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User entered '100.3' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99.4' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:11:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:01:44
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 5 (Day 5)'	Donna Toepfer (b) (4)	18 Aug 2020 23:00:02
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:13:36
User entered '13 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:13:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '16 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:07:25
User entered '17 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:13:36
User entered '100' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:13:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	20 Aug 2020 00:03:10
User entered empty.	System	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:13:36
	(b) (4)	
User entered '99.7' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:13:36
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '98.7' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Aug 2020 00:03:10
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	18 Aug 2020 23:00:02
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:13:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:13:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:03:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 6 (Day 6)'	Donna Toepfer (b) (4)	18 Aug 2020 23:00:02
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:14:34
User entered '14 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:14:34
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '17 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:07:25
User entered '18 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:14:34
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:14:34
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	20 Aug 2020 00:04:52
User entered empty.	System	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4)	18 Sep 2020 15:14:34
	(b) (4)	
User entered '98.3' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:14:34
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '97.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Aug 2020 00:04:52
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	18 Aug 2020 23:00:02
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:14:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:14:34
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:04:52
User entered empty.	Donna Toepfer (b) (4) (b) (4)	18 Aug 2020 23:00:02

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 7 (Day 7)'	Donna Toepfer (b) (4)	20 Aug 2020 00:08:04
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:15:16
User entered '15 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:15:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '18 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:15:16
User entered '98.4' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:15:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98.7' F	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:15:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:15:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:08:04

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 8 (Day 8)'	Donna Toepfer (b) (4)	20 Aug 2020 00:12:36
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:21:49
User entered '16 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:21:49
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '19 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:21:49
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:21:49
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	20 Aug 2020 00:12:36

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:21:49
User entered '98.7' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:21:49
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98.8' F	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	20 Aug 2020 00:12:36

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 9 (Day 9)'	Donna Toepfer (b) (4)	26 Aug 2020 21:45:33
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User entered '17 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '21 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User entered '97.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98.7' F	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Moderate (Moderate)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:23:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:45:33

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 10 (Day 10)'	Donna Toepfer (b) (4)	26 Aug 2020 21:47:03
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User entered '18 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '21 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User entered '98.7' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98.6' F	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:25:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Moderate (Moderate)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:47:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 11 (Day 11)'	Donna Toepfer (b) (4)	26 Aug 2020 21:48:01
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:27:31
User entered '19 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:27:31
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '22 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:27:31
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:27:31
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '100'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:27:31
User entered '98.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:27:31
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '98.6' F	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:27:31
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:27:31
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:48:01

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 12 (Day 12)'	Donna Toepfer (b) (4)	26 Aug 2020 21:49:00
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User entered '20 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '23 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User entered '98.7' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99.2' F	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:31:21
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:49:00

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 13 (Day 13)'	Donna Toepfer (b) (4)	26 Aug 2020 21:50:07
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User entered '21 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '24 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User entered '98.6' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99.8' F	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:32:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:50:07

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: Signature has been broken.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Day 14 (Day 14)'	Donna Toepfer (b) (4)	26 Aug 2020 21:51:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User entered '22 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '26 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User entered '100' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User entered '98.6' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '99.1' F	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:13:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:36:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	26 Aug 2020 21:51:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 15 (Day 15)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '23 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:56:55
	(b) (4)	
User entered '26 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:56:39
	(b) (4)	
User entered '97'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	31 Aug 2020 21:55:12

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '99.2' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:56:39
	(b) (4)	
User entered '98.8' F	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:55:12

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:55:12

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:55:12

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:55:12

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:56:39
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:55:12

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:56:39
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:55:12
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 16 (Day 16)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '24 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:57:43
	(b) (4)	
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '99'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	31 Aug 2020 21:56:47

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:57:43
	(b) (4)	
User entered '98.6' F	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:56:47

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:56:47

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:57:43
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:56:47

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:56:47

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:56:47

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:56:47
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 17 (Day 17)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
User closed query 'Per CDM: Per sponsor review - Symptom Log Dates are duplicate dates. Please review / verify and update dates between lines 17 and 18 of Symptom log, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:05:54
Query 'Per CDM: Per sponsor review - Symptom Log Dates are duplicate dates. Please review / verify and update dates between lines 17 and 18 of Symptom log, else clarify. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:15:39
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:15:27
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:15:27
User entered '25 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:15:27
User opened query 'Per CDM: Per sponsor review - Symptom Log Dates are duplicate dates. Please review / verify and update dates between lines 17 and 18 of Symptom log, else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 04:42:14
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '26 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 15:59:29
User entered '28 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:57:37

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:59:29
	(b) (4)	
User entered '98'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	31 Aug 2020 21:57:37

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '99' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:59:29
	(b) (4)	
User entered '98.8' F	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:57:37

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:57:37

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:59:29
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 15:59:29
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:57:37

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:57:37
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 18 (Day 18)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '26 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:00:30
	(b) (4)	
User entered '29 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '97' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:00:30
	(b) (4)	
User entered '98'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	31 Aug 2020 21:58:51

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:00:30
	(b) (4)	
User entered '98.3' F	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:58:51

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:00:30
	(b) (4)	
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:58:51

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:58:51
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 19 (Day 19)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
User closed query 'Per CDM: Per sponsor review - Symptom Log Date missing. Please review / verify and update missing date between Days 18 and 19 of Symptom log, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:09:29
Query 'Per CDM: Per sponsor review - Symptom Log Date missing. Please review / verify and update missing date between Days 18 and 19 of Symptom log, else clarify. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:22:07
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
User entered '27 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
User opened query 'Per CDM: Per sponsor review - Symptom Log Date missing. Please review / verify and update missing date between Days 18 and 19 of Symptom log, else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 04:43:36
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '28 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:01:23
User entered '30 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
User entered '98.6' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:21:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:01:23
User entered '98.6' F	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:01:23
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:59:49

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	31 Aug 2020 21:59:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 20 (Day 20)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:25:09
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:25:09
User entered '28 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:25:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '29 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:02:14
User entered '31 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:39:03

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	01 Sep 2020 23:39:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:25:09
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:25:09
User entered '98.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:25:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98.3' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:02:14
User entered '98.7' F	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:39:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:02:14
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:39:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:02:14
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:39:03

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:02:14
	(b) (4)	
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	01 Sep 2020 23:39:03
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 21 (Day 21)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User entered '29 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '30 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:04:49
User entered '1 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:40:08

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:04:49
	(b) (4)	
User entered '99'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	01 Sep 2020 23:40:08

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Mar 2021 13:37:09
User entered '98.3' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Mar 2021 13:37:01
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User entered '98.3.' (non-conformant).	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98.6' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:04:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 23:41:15
User entered '99.1' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:41:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 23:40:08
User entered '99.1' (non-conformant).	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:40:08

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:04:49
	(b) (4)	
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:40:08

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:04:49
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	01 Sep 2020 23:40:08

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	01 Sep 2020 23:40:08
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 22 (Day 22)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User entered '30 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '31 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:06:39
User entered '2 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 22:04:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:06:39
	(b) (4)	
User entered '99'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User entered '%'	(b) (4), (b) (6) System	02 Sep 2020 22:04:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User entered '98.6' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98.7' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:06:39
User entered '98.5' F	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 22:04:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 22:04:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 22:04:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 22:04:13

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:06:39
	(b) (4)	
User entered 'None (None)'	Donna Toepfer (b) (4)	02 Sep 2020 22:04:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 23 (Day 23)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:09:24
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User entered '31 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '01 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:09:24
User entered '09 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 15:57:53

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:09:24
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	18 Sep 2020 16:09:24
User entered empty.	System	10 Sep 2020 15:57:53

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '99.1' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:09:24
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 15:57:53

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 15:57:53

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

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Form: Symptom Log (23)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 15:57:53

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:57:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Day 24 (Day 24)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:10:10
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User entered '01 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:28:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:05:18
Query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08SEP2020. Please reconcile or clarify.' answered with 'Symptoms ended, so convalescence log ended ' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:38:41
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:37:07
User entered '02 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:37:07
User opened query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:00:37

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '2 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:10:10
	(b) (4)	
User entered '10 Aug 2020'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:10:10
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	18 Sep 2020 16:10:10
User entered empty.	System	10 Sep 2020 15:58:53

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User entered '99.1' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered '98.5' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:10:10
User entered '100.4' F	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 15:58:53

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:10:10
	(b) (4)	
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:10:10
	(b) (4)	
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 15:58:53

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 15:58:53

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:13:38
User entered 'None (None)'	Donna Toepfer (b) (4)	10 Sep 2020 15:58:53
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:21
	(b) (4)	
User entered 'Day 25 (Day 25)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Mar 2021 13:37:01
	(b) (4)	
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	16 Mar 2021 13:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	18 Sep 2020 16:11:01
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:00:09
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
User entered '02 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered '11 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered '0'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
User entered '99' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered empty.	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
	(b) (4), (b) (6)	
User entered '%'	System	16 Mar 2021 13:37:01
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	16 Mar 2021 13:19:39
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	18 Sep 2020 16:11:01
	(b) (4)	
User entered empty.	System	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
User entered '98.5' F reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:37:01
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered '99.1' F	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'None (None)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:06:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:05:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Mar 2021 12:24:21
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4) (b) (4)	16 Mar 2021 13:19:39
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4) (b) (4)	18 Sep 2020 16:11:01
User entered 'Mild (Mild)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:00:09

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
User closed query 'Per GCL LAB reconciliation: Saliva: Requery 1: Per response "I added, I hope I did it right", however the saliva form does not have Saliva dated 12AUG2020,however there is no data updated.Thanks ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Feb 2021 13:10:35
Query 'Per GCL LAB reconciliation: Saliva: Requery Donna Toepfer 1: Per response "I added, I hope I did it right", however the saliva form does not have Saliva dated 12AUG2020,however there is no data updated.Thanks ' answered with 'updated' (Site from DM).	(b) (4) (b) (4)	25 Jan 2021 16:42:38
User opened query 'Per GCL LAB reconciliation: Saliva: Requery 1: Per response "I added, I hope I did it right", however the saliva form does not have Saliva dated 12AUG2020,however there is no data updated.Thanks ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 06:38:23
User closed query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 12AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 12AUG2020 for this subject then update the Preclarus. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 06:38:23
Query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 12AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 12AUG2020 for this subject then update the Preclarus. Thank you. ' answered with 'I added, i hope i did it right??' (Site from DM).	(b) (4) (b) (4)	08 Jan 2021 23:40:03

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Date of Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 12AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 12AUG2020 for this subject then update the Preclarus. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 14:06:19
	(b) (4), (b) (6)	29 Sep 2020 16:14:25
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '12 Aug 2020'	Donna Toepfer (b) (4)	24 Aug 2020 20:56:38
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:14:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:56:38

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
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). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 19:34:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
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 'AE updated' (Site from System).	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:57:11
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	24 Aug 2020 20:56:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:56:38

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 12AUG2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please provide the correct Visit in the response. Also, update PPD portal as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 07:39:15
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 12AUG2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please provide the correct Visit in the response. Also, update PPD portal as appropriate. Else clarify, thank you.' answered with 'should be Covid-19 assessment.' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:25:06
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 12AUG2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please provide the correct Visit in the response. Also, update PPD portal as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:31:01
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '12 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:56:38

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:06:23
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	25 Mar 2021 18:09:01
User closed query 'Per GCL Lab Reconciliation: Swab: Per above response, "should be Covid-19 assessment."; however, corresponding swab sample is missing in EDC. Kindly consider updating the type of test performed, if swab sample was collected on 12-AUG-2020, as 12-AUG-2020, saliva test is already present in another covid-19 Assessment eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 04:31:53
Query 'Per GCL Lab Reconciliation: Swab: Per above response, "should be Covid-19 assessment."; however, corresponding swab sample is missing in EDC. Kindly consider updating the type of test performed, if swab sample was collected on 12-AUG-2020, as 12-AUG-2020, saliva test is already present in another covid-19 Assessment eCRF, else clarify.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	19 Mar 2021 14:19:26
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	19 Mar 2021 14:19:22
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	19 Mar 2021 14:19:22
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	19 Mar 2021 14:19:22
User opened query 'Per GCL Lab Reconciliation: Swab: Per above response, "should be Covid-19 assessment."; however, corresponding swab sample is missing in EDC. Kindly consider updating the type of test performed, if swab sample was collected on 12-AUG-2020, as 12-AUG-2020, saliva test is already present in another covid-19 Assessment eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:34:37

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

Type of Test Performed

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:25:27
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	25 Jan 2021 16:42:20
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	25 Jan 2021 16:42:20
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	25 Jan 2021 16:42:20
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:56:38

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:14:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:56:38

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[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)	29 Apr 2021 20:25:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:14:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:56:38

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:14:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:56:38

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 16:14:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:56:38

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:41
User entered 'I'	(b) (4), (b) (6) System	24 Aug 2020 20:56:38

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 22:33:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 22:33:55
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Sep 2020 22:33:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 22:33:45
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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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)	29 Apr 2021 20:25:48
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:33:45

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

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Generated On: 11 Aug 2021 22:06:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

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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)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Generated On: 11 Aug 2021 22:06:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:42
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 22:33:45
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:06:10

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:25:56
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:35:27
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:34:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:34:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:07:27
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	26 Oct 2020 19:30:12
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	26 Oct 2020 19:30:12
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	26 Oct 2020 19:30:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:14:56
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 20:51:29
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	13 Aug 2020 12:32:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	13 Aug 2020 12:32:09
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	12 Aug 2020 23:24:00

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:06:10

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	12 Aug 2020 23:23:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:16
User entered '10 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:37:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:16
User entered '22:05'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:37:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User entered '10 Aug 2020 22:05'	(b) (4), (b) (6) System	08 Jan 2021 23:37:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:16
User entered 'Safety Call (Safety Call)'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:37:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:10

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:16
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:37:23

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
User entered '12 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[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 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[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 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
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)	12 Jan 2021 09:06:32
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 'updated' (Site from System).	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:14
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	08 Jan 2021 23:39:06
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
User entered '12 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

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Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User closed query ' Per GCL LAB reconciliation: Saliva: Please note that 10aug2020 COVID Diagnostic Test is present for the Swab, however Saliva test is also reported on this page and which is not required. Hence please remove this page as it is duplicate entry. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Apr 2021 15:39:47
Query ' Per GCL LAB reconciliation: Saliva: Please note that 10aug2020 COVID Diagnostic Test is present for the Swab, however Saliva test is also reported on this page and which is not required. Hence please remove this page as it is duplicate entry. ' answered with 'add per instruction from Dm and monitor since swab was negative and saliva was positive' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	23 Mar 2021 20:18:41
User opened query ' Per GCL LAB reconciliation: Saliva: Please note that 10aug2020 COVID Diagnostic Test is present for the Swab, however Saliva test is also reported on this page and which is not required. Hence please remove this page as it is duplicate entry. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:06:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
User entered 'Saliva Test (Saliva Test)'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
User entered empty.	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[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 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
User entered empty.	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:06:10

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:26:22
User entered empty.	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:39:06

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Generated On: 11 Aug 2021 22:06:10

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
User entered 'I'	(b) (4), (b) (6) System	08 Jan 2021 23:39:06

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

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 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
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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 16:35:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	02 Mar 2021 22:00:12
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	25 Feb 2021 21:05:42

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[Start Date](#)

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	(b) (4)	

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
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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 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
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Did the subject have Respiratory failure?

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 14:07:17
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[Mechanical Ventilation?](#)

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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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[Evidence of Shock Requires
Vasopressors](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Radiographical Evidence](#)

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[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 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

US3242002

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:06:10

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:35:21
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 14:07:17
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	25 Feb 2021 21:05:42
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:06:10

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Donna Toepfer (b) (4)	08 Sep 2020 22:37:57
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:06:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14, 16, 18, 21, 26AUG2020 and 01SEP2020 are recorded under Illness Visit Day 3, 5, 7, 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 08:13:29
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14, 16, 18, 21, 26AUG2020 and 01SEP2020 are recorded under Illness Visit Day 3, 5, 7, 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 'confirmed receipt from lab' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	08 Dec 2020 13:03:23
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12AUG2020 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)	08 Dec 2020 06:39:32
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14, 16, 18, 21, 26AUG2020 and 01SEP2020 are recorded under Illness Visit Day 3, 5, 7, 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 08:24:38

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12AUG2020 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 'no saliva reported in source for 12Aug2020, day 3 is first day 14Aug2020' (Site from DM).	Donna Toepfer (b) (4) (b) (4) (b) (4)	04 Dec 2020 22:03:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12AUG2020 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) (b) (4)	04 Dec 2020 06:29:13
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	29 Sep 2020 16:17:46
User entered '14 Aug 2020'	Donna Toepfer (b) (4) (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:06:10

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Donna Toepfer (b) (4)	08 Sep 2020 22:37:57
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:06:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 16-AUG-2020 for Day 5 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 5 with accession number as 1F623253090 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 13:15:34
Query 'Per GCL Lab Recon: Saliva: Sample dated 16-AUG-2020 for Day 5 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 5 with accession number as 1F623253090 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' answered with 'Day 5 Saliva collection date is 16Aug2020; DCF has been submitted to Preclarus.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:46:59
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 16-AUG-2020 for Day 5 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 5 with accession number as 1F623253090 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:05:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:21:55
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with '1F63247' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	22 Jan 2021 13:28:46
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:50:40

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 16AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:50:00
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 16AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Fed Ex 9069 0787 1029' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:41:27
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 16AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:08:48
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered '16 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:06:10

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Donna Toepfer (b) (4)	08 Sep 2020 22:37:57
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:06:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 18-AUG-2020 for Day 7 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 7 with accession number as 1F600558764 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 13:15:42
Query 'Per GCL Lab Recon: Saliva: Sample dated 18-AUG-2020 for Day 7 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 7 with accession number as 1F600558764 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' answered with 'Day 7 collection date is 18Aug2020; DCF has been submitted to Preclarus.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:47:52
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 18-AUG-2020 for Day 7 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 7 with accession number as 1F600558764 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:08:59
Query 'Per GCL Lab Recon: Saliva: Sample dated 18-AUG-2020 for Day 7 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 5 with accession number as 1F600558764 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:08:48
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 18-AUG-2020 for Day 7 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 5 with accession number as 1F600558764 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:06:15

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM). Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with '1F63247' (Site from DM).	(b) (4), (b) (6) Donna Toepfer (b) (4) (b) (4)	25 Jan 2021 10:21:59 22 Jan 2021 13:31:01
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:50:52
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 18AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:50:05
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 18AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Fed ex 9069 0787 1029' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:41:44
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 18AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:09:19
User closed query 'Per GCL Lab Reconciliation: Swab Sample dated 18Aug2020 is recorded under Illness visit in EDC, however Saliva sample day 7 is also reported under Illness visit dated 12Aug2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:24:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab Sample dated 18Aug2020 is recorded under Illness visit in EDC, however Saliva sample day 7 is also reported under Illness visit dated 12Aug2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	26 Oct 2020 19:31:37
User opened query 'Per GCL Lab Reconciliation: Swab Sample dated 18Aug2020 is recorded under Illness visit in EDC, however Saliva sample day 7 is also reported under Illness visit dated 12Aug2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 19:12:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered '18 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:06:10

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Donna Toepfer (b) (4)	08 Sep 2020 22:37:57
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:06:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 21-AUG-2020 for Day 9 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 9 with accession number as 1F616891050 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 13:15:46
Query 'Per GCL Lab Recon: Saliva: Sample dated 21-AUG-2020 for Day 9 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 9 with accession number as 1F616891050 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' answered with 'Day 9 Saliva is 21Aug2020; DCF has been sent to Preclarus.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:48:31
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 21-AUG-2020 for Day 9 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 9 with accession number as 1F616891050 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:08:41
Query 'Per GCL Lab Recon: Saliva: Sample dated 21-AUG-2020 for Day 9 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 5 with accession number as 1F616891050 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:08:30
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 21-AUG-2020 for Day 9 is recorded in EDC, however sample is reported with 12-AUG-2020 for Day 5 with accession number as 1F616891050 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:07:08

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:22:03
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with '1F63247' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	22 Jan 2021 13:29:51
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:50:58
User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 21AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:50:58
Query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 21AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Fed Ex 9069 0787 1018' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:41:57
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 21AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:09:51
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered '21 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:06:10

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Donna Toepfer (b) (4)	08 Sep 2020 22:37:57
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:06:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 26-AUG-2020 for Day 14 is recorded in EDC, however sample is reported with 08-SEP-2020 for Day 14 with accession number as 1F606876834 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 13:15:51
Query 'Per GCL Lab Recon: Saliva: Sample dated 26-AUG-2020 for Day 14 is recorded in EDC, however sample is reported with 08-SEP-2020 for Day 14 with accession number as 1F606876834 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' answered with 'Day 14 Saliva is 26Aug2020; DCF has been sent to Preclarus' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:48:57
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 26-AUG-2020 for Day 14 is recorded in EDC, however sample is reported with 08-SEP-2020 for Day 14 with accession number as 1F606876834 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:08:20
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:22:07
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with '1F63247' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	22 Jan 2021 16:38:42
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:51:11

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 26AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:51:11
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 26AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Fed Ex 9069 0787 0993' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:42:10
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 26AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:10:56
User closed query 'Per GCL Lab Reconciliation: Saliva Sample dated 26Aug2020 is recorded under Illness visit in EDC, however Saliva sample day 14 is also reported under Illness visit dated 08Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:26:28
Query 'Per GCL Lab Reconciliation: Saliva Sample dated 26Aug2020 is recorded under Illness visit in EDC, however Saliva sample day 14 is also reported under Illness visit dated 08Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	26 Oct 2020 19:31:59
User opened query 'Per GCL Lab Reconciliation: Saliva Sample dated 26Aug2020 is recorded under Illness visit in EDC, however Saliva sample day 14 is also reported under Illness visit dated 08Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 19:14:48
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Donna Toepfer (b) (4)	08 Sep 2020 22:37:57
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:06:10

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Donna Toepfer (b) (4)	08 Sep 2020 22:37:57
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:06:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 1-SEP-2020 for Day 21 is recorded in EDC, however sample is reported with 08-SEP-2020 for Day 21 with accession number as 1F617365162 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 13:15:56
Query 'Per GCL Lab Recon: Saliva: Sample dated 1-SEP-2020 for Day 21 is recorded in EDC, however sample is reported with 08-SEP-2020 for Day 21 with accession number as 1F617365162 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you.' answered with 'Day 21 collection is 01Sep2020; DCF has been sent to Preclarus.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:49:24
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 1-SEP-2020 for Day 21 is recorded in EDC, however sample is reported with 08-SEP-2020 for Day 21 with accession number as 1F617365162 in PPD Central lab. Please confirm the correct date and accession number for the sample and update EDC or Preclarus as applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 08:10:27
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:22:11
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with '1F63247' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	22 Jan 2021 16:38:53
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:51:17

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 01SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:51:17
Query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 01SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Fed Ex 9069 0787 0960' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	08 Jan 2021 23:42:25
User opened query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 01SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:11:27
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered '1 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:06:10

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Donna Toepfer (b) (4)	08 Sep 2020 22:37:57
	(b) (4)	

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:06:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per GCL Reconciliation: Saliva sample collected on 08SEP2020 is labelled under "Unscheduled Visit" in Viracor data and in GCL it is labelled under "Convisit D28". Please verify the correct visit for sample collected on this date. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:34:12
Query 'Per GCL Reconciliation: Saliva sample collected on 08SEP2020 is labelled under "Unscheduled Visit" in Viracor data and in GCL it is labelled under "Convisit D28". Please verify the correct visit for sample collected on this date. ' answered with 'should be Con visit D28' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	03 Nov 2020 14:41:52
User opened query 'Per GCL Reconciliation: Saliva sample collected on 08SEP2020 is labelled under "Unscheduled Visit" in Viracor data and in GCL it is labelled under "Convisit D28". Please verify the correct visit for sample collected on this date. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:38:51
Query 'Per GCL Reconciliation: Swab sample collected on 08SEP2020 is labelled under "Unscheduled Visit" in Viracor data and in GCL it is labelled under "Convisit D28". Please verify the correct visit for sample collected on this date.' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:38:42
User opened query 'Per GCL Reconciliation: Swab sample collected on 08SEP2020 is labelled under "Unscheduled Visit" in Viracor data and in GCL it is labelled under "Convisit D28". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:37:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:46
User entered '8 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:37:57

US3242002

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 12AUG2020, however, this sample is not recorded in the CRF. Please enter the correct data in the Covid-19 Assessment folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 22:10:53
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, Donna Toepfer there is a Swab sample with a Collection Date of 12AUG2020, however, this sample is not recorded in the CRF. Please enter the correct data in the Covid-19 Assessment folder, as appropriate.' answered with 'captured under covid-19 10 aug 2020, diagnostic test is 12 aug 2020' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	28 Dec 2020 17:22:37
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 12AUG2020, however, this sample is not recorded in the CRF. Please enter the correct data in the Covid-19 Assessment folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:23:39
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:02:10

US3242002

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '12 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:02:10

US3242002

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[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 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:02:10

US3242002

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
User entered 'SICKD1'	System	24 Aug 2020 21:02:10

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	24 Aug 2020 21:03:40
	(b) (4)	

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '12 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '17:46'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
User entered '12 Aug 2020 17:46'	System	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '62' in	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40
DataPoint set to visible.	System	24 Aug 2020 21:02:10

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '230' lb	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40
DataPoint set to visible.	System	24 Aug 2020 21:02:10

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '99.4' F	Donna Toepfer (b) (4)	24 Aug 2020 21:03:40
	(b) (4)	

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Oral (Oral)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '116'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
User entered 'bpm'	System	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '18'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
User entered 'breaths/min'	System	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '122'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
User entered 'mmHg'	System	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '82'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
User entered 'mmHg'	System	24 Aug 2020 21:03:40

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28

US3242002

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28

US3242002

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:40
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:03:59

US3242002

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:40
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Aug 2020 21:08:36
User entered '12 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Aug 2020 21:08:36
	(b) (4)	
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Aug 2020 21:03:59
User entered '24 Aug 2020'	Donna Toepfer (b) (4)	24 Aug 2020 21:03:59
	(b) (4)	

US3242002

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
User closed query 'Per GCL Lab Reconciliation:SARS - CoV2: Sample dated 12AUG2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:34:59
Query 'Per GCL Lab Reconciliation:SARS - CoV2: Sample dated 12AUG2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'correct visit us SARS-CoV2' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	28 Oct 2020 12:13:24
User opened query 'Per GCL Lab Reconciliation:SARS - CoV2: Sample dated 12AUG2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:41:59
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:04:22

US3242002

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:16:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '12 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:04:22

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:54
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:34:18

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:54
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:38:05
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 22:33:18
User entered '08 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 22:33:18
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:01
User entered '8 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:34:18

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[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 21:28:54
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:01
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:34:18

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:54
User entered 'SICKD28'	System	08 Sep 2020 22:34:18

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '8 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '10:01'	Donna Toepfer (b) (4)	08 Sep 2020 22:35:01
	(b) (4)	

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User entered '8 Sep 2020 10:01'	System	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '62' in	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01
DataPoint set to visible.	System	08 Sep 2020 22:34:18

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '230' lb	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01
DataPoint set to visible.	System	08 Sep 2020 22:34:18

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '97.9' F	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered 'Oral (Oral)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered empty.	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '80'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User entered 'bpm'	System	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '14'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User entered 'breaths/min'	System	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '124'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User entered 'mmHg'	System	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:09
User entered '76'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59
User entered 'mmHg'	System	08 Sep 2020 22:35:01

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:59

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:27
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:12

US3242002

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:27
User entered '8 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:12

US3242002

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:06:10

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:35
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:32

US3242002

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:06:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:17:35
User entered '8 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	08 Sep 2020 22:35:32

US3242002

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

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:14:12

US3242002

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

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 23:14:12
	(b) (4)	

US3242002

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

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	12 Jan 2021 23:14:12
	(b) (4)	

US3242002

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

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	12 Jan 2021 23:14:12

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 23:14:47
	(b) (4)	

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:54:41
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:27:58

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:14:47

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:54:41
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:27:58

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 23:14:47
	(b) (4)	

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Placebo (Placebo)'	Erynn McKinley (b) (4)	12 Jan 2021 23:14:47
	(b) (4)	

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:17:06
User entered 'Placebo (Placebo)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:14:47

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:17:06
User entered 'Placebo (Placebo)'	Erynn McKinley (b) (4)	12 Jan 2021 23:14:47
	(b) (4)	

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	12 Jan 2021 23:14:47
	(b) (4)	

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 23:14:47

US3242002

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:10

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 23:14:47

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Erynn McKinley (b) (4)	13 Jan 2021 19:45:19
change Data Entry Error	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Erynn McKinley (b) (4)	13 Jan 2021 19:45:19
change Data Entry Error	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 23:18:53
DataPoint set to visible.	System	12 Jan 2021 23:14:47

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Erynn McKinley (b) (4)	13 Jan 2021 19:45:19
change Data Entry Error	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Erynn McKinley (b) (4)	13 Jan 2021 19:45:19
change Data Entry Error	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User entered empty.	System	12 Jan 2021 23:18:53
DataPoint set to visible.	System	12 Jan 2021 23:14:47

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '16:52'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '12 Jan 2021 16:52'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '97.9' F	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '80'	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'bpm'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '16'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '122'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mmHg'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '68'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mmHg'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Erynn McKinley (b) (4)	13 Jan 2021 19:45:19
change Data Entry Error	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Erynn McKinley (b) (4)	13 Jan 2021 19:45:19
change Data Entry Error	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 23:18:53
DataPoint set to visible.	System	12 Jan 2021 23:14:47

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '18:12'	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '12 Jan 2021 18:12'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '98.1' F	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '80'	Erynn McKinley (b) (4)	12 Jan 2021 23:18:53
	(b) (4)	

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'bpm'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '16'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '124'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mmHg'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '70'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:18:53

US3242002

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mmHg'	(b) (4), (b) (6) System	12 Jan 2021 23:18:53

US3242002

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:19:03

US3242002

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:19:03
	(b) (4)	

US3242002

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	12 Jan 2021 23:19:16
	(b) (4)	

US3242002

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 23:19:16
	(b) (4)	

US3242002

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Urine (URINE)'	Erynn McKinley (b) (4)	12 Jan 2021 23:19:16
	(b) (4)	

US3242002

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Negative (NEGATIVE)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:19:16

US3242002

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:19:16
	(b) (4)	

US3242002

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:19:16

US3242002

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:19:16

US3242002

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6) System	12 Jan 2021 23:19:16

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	12 Jan 2021 23:19:39
	(b) (4)	

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 23:19:39
	(b) (4)	

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:19:39

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mRNA-1273'	(b) (4), (b) (6)	
	System	12 Jan 2021 23:19:39
DataPoint set to visible.	System	12 Jan 2021 23:14:47

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:19:39

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '17:40'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:19:39

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '12 Jan 2021 17:40'	(b) (4), (b) (6) System	12 Jan 2021 23:19:39

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Erynn McKinley (b) (4)	12 Jan 2021 23:19:39
	(b) (4)	

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'ONCE'	(b) (4), (b) (6) System	12 Jan 2021 23:19:39

US3242002

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

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	12 Jan 2021 23:19:39

US3242002

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:15:09

US3242002

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:15:09

US3242002

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '16:27'	Erynn McKinley (b) (4)	12 Jan 2021 23:15:09
	(b) (4)	

US3242002

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '12 Jan 2021 16:27'	(b) (4), (b) (6) System	12 Jan 2021 23:15:09

US3242002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:15:21

US3242002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:06:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 23:15:21
	(b) (4)	

US3242002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:06:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered '16:16'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:15:21

US3242002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '12 Jan 2021 16:16'	(b) (4), (b) (6) System	12 Jan 2021 23:15:21

US3242002

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

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 23:15:24

US3242002

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

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 23:15:24

US3242002

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 15:29:03
	(b) (4)	

US3242002

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 15:29:03
	(b) (4)	

US3242002

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	19 Jan 2021 15:29:03
	(b) (4)	

US3242002

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Jan 2021 15:29:03
	(b) (4)	

US3242002

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 15:29:30
	(b) (4)	

US3242002

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'I'	(b) (4), (b) (6) System	19 Jan 2021 15:29:30

US3242002

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User entered '1'	System	19 Jan 2021 15:29:30
DataPoint set to visible.	System	19 Jan 2021 15:29:30

US3242002

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:34:12
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Feb 2021 21:46:14
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	15 Feb 2021 22:12:56
	(b) (4)	
User entered '15 Feb 2021' reason for change: Data Entry Error	Erynn McKinley (b) (4)	15 Feb 2021 22:12:56
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:12
	(b) (4)	
User entered '9 Feb 2021'	Erynn McKinley (b) (4)	09 Feb 2021 21:46:14
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:34:12
	(b) (4)	
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	09 Feb 2021 21:46:14
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'OLD29'	(b) (4), (b) (6) System	09 Feb 2021 21:46:14

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered '15 Feb 2021'	Erynn McKinley (b) (4)	15 Feb 2021 22:14:11
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '16:52'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '15 Feb 2021 16:52'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered '97.9' F	Erynn McKinley (b) (4)	15 Feb 2021 22:14:11
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	15 Feb 2021 22:14:11
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered '80'	Erynn McKinley (b) (4)	15 Feb 2021 22:14:11
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'bpm'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '16'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '122'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mmHg'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '68'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mmHg'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered '15 Feb 2021'	Erynn McKinley (b) (4)	15 Feb 2021 22:14:11
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '18:12'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '15 Feb 2021 18:12'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '98.1' F	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	15 Feb 2021 22:14:11
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered '80'	Erynn McKinley (b) (4)	15 Feb 2021 22:14:11
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'bpm'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '16'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '124'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mmHg'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '70'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mmHg'	(b) (4), (b) (6) System	15 Feb 2021 22:14:11

US3242002

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:16

US3242002

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	15 Feb 2021 22:14:16
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	15 Feb 2021 22:14:37
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered '15 Feb 2021'	Erynn McKinley (b) (4)	15 Feb 2021 22:14:37
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Urine (URINE)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:37

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Negative (NEGATIVE)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:37

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered 'No (N)'	Erynn McKinley (b) (4)	15 Feb 2021 22:14:37
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:37

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	15 Feb 2021 22:14:37
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6) System	15 Feb 2021 22:14:37

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:55

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	15 Feb 2021 22:14:55
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	15 Feb 2021 22:14:55
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'mRNA-1273'	(b) (4), (b) (6)	15 Feb 2021 22:14:55
DataPoint set to visible.	System	19 Jan 2021 15:29:30

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:05
	(b) (4)	
User entered '15 Feb 2021'	Erynn McKinley (b) (4)	15 Feb 2021 22:14:55
	(b) (4)	

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered '17:40'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:55

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '15 Feb 2021 17:40'	(b) (4), (b) (6) System	15 Feb 2021 22:14:55

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Left Arm (LEFT ARM)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:55

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'ONCE'	(b) (4), (b) (6) System	15 Feb 2021 22:14:55

US3242002

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:10

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	15 Feb 2021 22:14:55

US3242002

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 18:37:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	17 Feb 2021 17:19:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	15 Feb 2021 22:14:59

US3242002

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '1'	(b) (4), (b) (6) System	15 Feb 2021 22:14:59

US3242002

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Feb 2021 21:01:51
	(b) (4)	

US3242002

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered '22 Feb 2021'	Erynn McKinley (b) (4)	23 Feb 2021 21:01:51
	(b) (4)	

US3242002

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	23 Feb 2021 21:01:51

US3242002

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	02 Mar 2021 22:00:12
User entered empty.	Erynn McKinley (b) (4) (b) (4)	23 Feb 2021 21:01:51

US3242002

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:00:12
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Feb 2021 21:01:59
	(b) (4)	

US3242002

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'I'	(b) (4), (b) (6) System	23 Feb 2021 21:01:59

US3242002

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Mar 2021 21:45:36
	(b) (4)	

US3242002

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 16:15:48
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'out of window due to schedule conflict' (Site from System).	Donna Toepfer (b) (4) (b) (4)	08 Mar 2021 22:40:36
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Mar 2021 21:45:36
User entered '08 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:36

US3242002

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	08 Mar 2021 21:45:36
	(b) (4)	

US3242002

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered 'OLD57'	(b) (4), (b) (6) System	08 Mar 2021 21:45:36

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	08 Mar 2021 21:45:53
	(b) (4)	

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered empty.	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6) System	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	08 Mar 2021 21:45:53
	(b) (4)	

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered empty.	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered empty.	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	08 Mar 2021 21:45:53
	(b) (4)	

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6) System	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered empty.	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6) System	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered empty.	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6) System	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered empty.	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered empty.	(b) (4), (b) (6) System	08 Mar 2021 21:45:53

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 09:45:21

US3242002

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 09:45:21

US3242002

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:45:58

US3242002

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	08 Mar 2021 21:45:58
	(b) (4)	

US3242002

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:24:42
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Mar 2021 21:46:12
	(b) (4)	

US3242002

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered '08 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:46:12

US3242002

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	11 Mar 2021 00:24:42
User entered '16:35'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 21:46:12

US3242002

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:45:21
User entered '08 Mar 2021 16:35'	(b) (4), (b) (6) System	08 Mar 2021 21:46:12

US3242002

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:06:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:53
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:48
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:01:44

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:28:38
User entered 'USA-US067-2020-mRNA-1273-P301000001'	System	20 Aug 2020 14:20:46
User entered 'New'	(b) (4), (b) (6)	20 Aug 2020 14:20:46

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:05:03
User closed query 'Per CDM: per sponsor review, Please consider updating term to COVID-19' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:37:01
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 14:32:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 14:32:00
Data point term sent to Coder	System	16 Nov 2020 14:30:15
Query 'Per CDM: per sponsor review, Please consider updating term to COVID-19' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	16 Nov 2020 14:30:11
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	16 Nov 2020 14:30:04
Coding entries removed.	Donna Toepfer (b) (4) (b) (4)	16 Nov 2020 14:30:04
User entered 'COVID-19' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	16 Nov 2020 14:30:04
User opened query 'Per CDM: per sponsor review, Please consider updating term to COVID-19' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 14:13:12
User closed query 'Please review source and add AE of Sneezing that began on 09AU2020 as indicated. ' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 15:32:51
Query 'Please review source and add AE of Sneezing that began on 09AU2020 as indicated. ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:26:22
User opened query 'Please review source and add AE of Sneezing that began on 09AU2020 as indicated. ' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:06:36
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:02:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:02:11
Data point term sent to Coder	System	18 Aug 2020 20:59:30
Coding entries removed.	Donna Toepfer (b) (4)	18 Aug 2020 20:58:36
	(b) (4)	
User entered 'CoVid 19 Disease' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Aug 2020 20:58:36
	(b) (4)	
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:10:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:10:30
Data point term sent to Coder	System	14 Aug 2020 20:03:30
User entered 'Upper respiratory infection'	Donna Toepfer (b) (4)	14 Aug 2020 20:02:48
	(b) (4)	
	(b) (4)	

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	25 Aug 2020 22:28:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:26:46

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User closed query 'PV Query: As the patient was afebrile and asymptomatic on 09 Aug 2020, please consider updating event start date to 10 Aug 2020 (the first day of documented symptoms). If patient had symptoms on 09 Aug 2020, please provide.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 20:21:46
Query 'PV Query: As the patient was afebrile and asymptomatic on 09 Aug 2020, please consider updating event start date to 10 Aug 2020 (the first day of documented symptoms). If patient had symptoms on 09 Aug 2020, please provide.' answered with 'Per progress note from coordinator, subject has symptoms after doing diary. reports sneezing and cough' (Site from Safety).	Donna Toepfer (b) (4) (b) (4)	31 Aug 2020 21:53:06
User opened query 'PV Query: As the patient was afebrile and asymptomatic on 09 Aug 2020, please consider updating event start date to 10 Aug 2020 (the first day of documented symptoms). If patient had symptoms on 09 Aug 2020, please provide.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 19:32:16
User closed query 'PV Query: Please clarify the start date of 09Aug2020. In the Covid-19 assessment log, the first date listed with a fever and symptoms is 12Aug2020.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 16:00:06
Query 'PV Query: Please clarify the start date of 09Aug2020. In the Covid-19 assessment log, the first date listed with a fever and symptoms is 12Aug2020.' answered with 'per source phone call and diary, start on 09 Aug 2020' (Site from Safety).	Donna Toepfer (b) (4) (b) (4)	24 Aug 2020 21:07:27
User opened query 'PV Query: Please clarify the start date of 09Aug2020. In the Covid-19 assessment log, the first date listed with a fever and symptoms is 12Aug2020.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:46:39
User entered '09 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
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	15 Aug 2020 12:20:38
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 12:20:38
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	14 Aug 2020 20:02:48
User entered '21:00'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 12:20:38
User entered '09 Aug 2020 21:00'	System	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:53:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User closed query 'PV Query: Please provide the event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 01:16:07
Query 'PV Query: Please provide the event end date, when available.' answered with 'update' (Site from Safety).	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:53:53
User entered '02 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:53:46
User opened query 'PV Query: Please provide the event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:47:51
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
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	02 Sep 2020 21:54:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 21:54:15
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:54:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 21:53:46
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	02 Sep 2020 21:53:46
User entered 'un:uk' (non-conformant).	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:53:46
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 21:54:15
User entered '02 Sep 2020 UN:UK' (non-conformant).	System	02 Sep 2020 21:53:46
User entered empty.	System	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:18:25
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
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	02 Sep 2020 21:53:46
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:30:24
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	09 Dec 2020 16:15:44
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	09 Dec 2020 16:15:44
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:27:39
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:19:52
User entered 'None (NONE)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:19:52
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
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)	10 Sep 2020 16:27:14
User closed query 'PV Query: Please confirm action taken as none. Will the subject be continuing in the study? If no, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 01:15:56
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 'says due to SARS COVID' (Site from System).	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:55:30
Query 'PV Query: Please confirm action taken as none. Will the subject be continuing in the study? If no, please update action taken to withdrawn.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:54:34
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	02 Sep 2020 21:53:46

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:53:46
User opened query 'PV Query: Please confirm action taken as none. Will the subject be continuing in the study? If no, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 19:31:41
User entered 'None (NONE)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

None

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 01:15:33
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:55:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:53:46
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:48:11
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 12:20:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 12:20:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 12:20:38
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:02:48
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:01:29
User entered 'SUBJECT WAS NEGATIVE AT BASELINE SWAB AND REPORTS THAT SHE WAS NOT IN CONTACT WITH ANYONE THAT HAD COVID SYMPTOMS. Subject states her symptoms started on Aug 9, after she had completed her diary, so symptoms were not recorded in diary on Aug 9. Start date of AE will be Aug 9, since that is when she said the cough and sneezing initially started. (This is per coordinator source progress note)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	09 Sep 2020 20:14:54
User closed query 'PV Query: Please indicate if subject of any COVID contact between IP administration and start of the symptoms.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 01:15:48
User closed query 'PV Query: Please provide the results of the nasopharyngeal COVID test taken on 06 Aug 2020 prior to IP administration.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 01:15:44
Query 'PV Query: Please indicate if subject of any COVID contact between IP administration and start of the symptoms.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:55:46
Query 'PV Query: Please provide the results of the nasopharyngeal COVID test taken on 06 Aug 2020 prior to IP administration.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:55:42
User entered 'subject was negative at baseline swab and reports that she was not in contact with anyone that had Covid symptoms' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	02 Sep 2020 21:53:46
Query 'PV Query: The concomitant medication log lists Acetaminophen as being given for fever from 10-11Aug2020 although no fever is documented in the Covid-19 assessment log. Please clarify.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 19:32:46

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: A safety assessment call was made on 10Aug2020 that confirmed the subject had symptoms; please clarify what symptoms the subject experienced.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 19:32:40
User opened query 'PV Query: Please indicate if subject of any COVID contact between IP administration and start of the symptoms.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:48:24
User opened query 'PV Query: The concomitant medication log lists Acetaminophen as being given for fever from 10-11Aug2020 although no fever is documented in the Covid-19 assessment log. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:47:19
User opened query 'PV Query: A safety assessment call was made on 10Aug2020 that confirmed the subject had symptoms; please clarify what symptoms the subject experienced.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:46:58
User opened query 'PV Query: Please provide the results of the nasopharyngeal COVID test taken on 06 Aug 2020 prior to IP administration.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:46:18
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:02:48

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 02:26:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:26:46

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 02:26:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:26:46

US3242002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:26:46

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 17:59:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 17:59:38
Data point term sent to Coder	System	08 Feb 2021 17:58:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:37:58
Data point term sent to Coder	System	25 Sep 2020 17:36:56
User entered 'Fatigue'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 13:01:31
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 13:01:31
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '13 Aug 2020'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
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	25 Sep 2020 17:37:18
User entered empty; reason for change Data Entry Error	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:37:18
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	25 Sep 2020 17:36:45
User entered '21:16'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User entered empty.	System	25 Sep 2020 17:37:18
User entered '13 Aug 2020 21:16'	System	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '13 Aug 2020'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User entered empty.	System	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'None (NONE)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'I'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User entered '0'	System	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01
User entered '0'	System	25 Sep 2020 17:36:45

US3242002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:01

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Sneezing, LLT: Sneezing - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 17:59:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 17:59:35
Data point term sent to Coder	System	08 Feb 2021 17:58:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per DM CLR: Please review if this AE is related to the MH condition of Allergic Rhinitis. If related, verify if this is a worsening of the MH condition. If yes, please update to reflect worsening of the condition as appropriate and ensure that the severity is greater than Grade 1/Mild. Please update applicable details as appropriate. Otherwise, clarify.	(b) (4), (b) (6)	28 Oct 2020 20:11:29
' (Site from DM).		
Query 'Per DM CLR: Please review if this AE is related to the MH condition of Allergic Rhinitis. If related, verify if this is a worsening of the MH condition. If yes, please update to reflect worsening of the condition as appropriate and ensure that the severity is greater than Grade 1/Mild. Please update applicable details as appropriate. Otherwise, clarify.	Donna Toepfer (b) (4) (b) (4)	12 Oct 2020 12:09:12
' answered with 'added per monitor, symptom of URI' (Site from DM).		
User opened query 'Per DM CLR: Please review if this AE is related to the MH condition of Allergic Rhinitis. If related, verify if this is a worsening of the MH condition. If yes, please update to reflect worsening of the condition as appropriate and ensure that the severity is greater than Grade 1/Mild. Please update applicable details as appropriate. Otherwise, clarify.	(b) (4), (b) (6)	12 Oct 2020 04:53:07
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Sneezing, LLT: Sneezing - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 19:29:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 19:29:59
Data point term sent to Coder	System	25 Sep 2020 19:28:44
User entered 'Sneezing'	Donna Toepfer (b) (4)	25 Sep 2020 19:27:52
	(b) (4)	

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '9 Aug 2020'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Donna Toepfer (b) (4)	25 Sep 2020 19:27:52
	(b) (4)	

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User entered empty.	System	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '11 Aug 2020'	Donna Toepfer (b) (4)	25 Sep 2020 19:27:52
	(b) (4)	

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User entered empty.	System	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'None (NONE)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered '0'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:12
User entered empty.	Donna Toepfer (b) (4) (b) (4)	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User entered '0'	System	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05
User entered '0'	System	25 Sep 2020 19:27:52

US3242002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:06:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:38:05

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:06:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:53
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:27
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	07 Aug 2020 12:43:38

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:46:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:46:14
Data point term sent to Coder	System	07 Aug 2020 12:44:54
User entered 'Albuterol'	Donna Toepfer (b) (4) (b) (4)	07 Aug 2020 12:44:41

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Asthma'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '90'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'ug (ug)'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
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)	10 Aug 2020 17:08:27
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.'	Donna Toepfer (b) (4)	07 Aug 2020 12:46:17
answered with 'per guildelines, medications should be entered' (Site from System).	(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	07 Aug 2020 12:44:41
User entered 'UN Jan 1990'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:44:41
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:44:41

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:44:41

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:44:41

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Aug 2020 12:49:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Aug 2020 12:49:07
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 12:47:55
User entered 'Trazadone'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Insomnia'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '50'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'mg (mg)'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
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)	10 Aug 2020 17:08:40
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.'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:27
answered with 'per guidelines, should be entered' (Site from System).	(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	07 Aug 2020 12:47:10
User entered 'UN Jan 2015'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 13:41:26
User closed query "'Per CDM: Was this medication taken for solicited event? indicated as 'Yes' or 'No' as per CCGs Guidelines, kindly select Yes or No response else clarify, Thank You' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 13:41:23
Query "'Per CDM: Was this medication taken for solicited event? indicated as 'Yes' or 'No' as per CCGs Guidelines, kindly select Yes or No response else clarify, Thank You' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	24 Aug 2020 11:42:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Aug 2020 11:42:48
	(b) (4)	
User opened query "'Per CDM: Was this medication taken for solicited event? indicated as 'Yes' or 'No' as per CCGs Guidelines, kindly select Yes or No response else clarify, Thank You' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 10:19:00
Query 'Data is required. Please complete.' answered with 'per guidelines, should be entered' (Site from System).	Donna Toepfer (b) (4)	07 Aug 2020 12:47:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 12:47:10
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:47:10
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:47:10

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:47:10

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:47:10

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
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, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: DEPO PROVERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 19:36:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 19:36:47
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 19:35:48
Coding entries removed.	Donna Toepfer (b) (4)	04 Sep 2020 19:35:43
	(b) (4)	
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
	(b) (4)	
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, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: DEPO PROVERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 23:57:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 23:57:17
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 12:50:59
User entered 'Depo Provera'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:27:46
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:44
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:36:41
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:36:33
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:36:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:36:33
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:04:42
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Birth control'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:43
User entered '104' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '1'	Donna Toepfer (b) (4) (b) (4)	07 Aug 2020 12:50:31

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:43
User entered 'mg (mg)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:43
Query 'Per cdm: kindly review answers and update per available options", else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 16:31:56
User opened query 'Per cdm: kindly review answers and update per available options", else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 16:31:20
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Other (OTHER)'	Donna Toepfer (b) (4) (b) (4)	07 Aug 2020 12:50:31

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User closed query 'Per cdm: kindly review answers and update per available options", else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:59:43
Query 'Per cdm: kindly review answers and update per available options", else clarify.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:51
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:43
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:43
User opened query 'Per cdm: kindly review answers and update per available options", else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 16:32:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Injection'	Donna Toepfer (b) (4) (b) (4)	07 Aug 2020 12:50:31

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'other (OTHER)'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Every 3 month'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:43
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	04 Sep 2020 19:35:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Intramuscular (INTRAMUSCULAR)'	Donna Toepfer (b) (4) (b) (4)	07 Aug 2020 12:50:31

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
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)	10 Aug 2020 17:10:01
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.'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:39
answered with 'per guidelines, should be entered' (Site from System).	(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	07 Aug 2020 12:50:31
User entered '01 Oct 2012'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:50:31
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:50:31

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:50:31

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:50:31

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:52:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:52:10
Data point term sent to Coder	System	07 Aug 2020 12:51:59
User entered 'Sertraline'	Donna Toepfer (b) (4) (b) (4)	07 Aug 2020 12:51:26

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Anxiety'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '50'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'mg (mg)'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
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)	10 Aug 2020 17:10:19
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.'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:31
answered with 'per guidelines, should be entered' (Site from System).	(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	07 Aug 2020 12:51:26
User entered 'UN Jan 2015'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:51:26
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:51:26

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:51:26

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:51:26

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 13:12:10
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 13:12:10
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 12:53:00
User entered 'Loratadine'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Seasonal allergic rhinitis'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '10'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'mg (mg)'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
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)	10 Aug 2020 17:10:35
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.'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:23
answered with 'per guidelines, should be entered' (Site from System).	(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	07 Aug 2020 12:52:15
User entered '01 Jan 1990'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:52:15
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:52:15

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:52:15

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:52:15

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:30:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:30:47
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 12:54:01
User entered 'Flovent HFA'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Asthma'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '110'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'ug (ug)'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:49:06
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:33:09
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:33:09
User entered 'as needed (PRN)' reason for change: New Information	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:33:09
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'once daily (QD)'	Donna Toepfer (b) (4) (b) (4)	07 Aug 2020 12:53:13

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
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)	10 Aug 2020 17:11:20
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.'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:26
answered with 'per guidelines, should be entered' (Site from System).	(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	07 Aug 2020 12:53:13
User entered 'UN UNK 2019'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 12:53:13
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 15:33:09
User entered '1'	System	07 Aug 2020 12:53:13

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 15:33:09
User entered '1'	System	07 Aug 2020 12:53:13

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 15:33:09
User entered '804 (804)'	System	07 Aug 2020 12:53:13

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 15:37:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Nov 2020 15:37:04
Data point term sent to Coder	System	19 Nov 2020 15:36:41
Coding entries removed.	Erynn McKinley (b) (4)	19 Nov 2020 15:35:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 17:05:36
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	09 Nov 2020 17:04:59
	Donna Toepfer (b) (4)	09 Nov 2020 17:03:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	(b) (4)	
	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 14:58:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 14:56:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Acetaminophen'	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49
	(b) (4)	

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:49:06
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:35:53
User entered 'COVID-19 (Symptoms)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:35:53
User closed query 'Per DM CLR RQ: Response to previous query noted. However, please confirm if this SOLICITED ADVERSE REACTION OF FEVER DID NOT MEET THE AE REPORTING CRITERIA. Else, if this meets AE reporting criteria per protocol a corresponding AE should be recorded.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:36:09
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:14:07
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 17:03:58
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 17:03:58
User entered 'COVID-19' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 17:03:58
Query 'Per DM CLR RQ: Response to previous query noted. However, please confirm if this SOLICITED ADVERSE REACTION OF FEVER DID NOT MEET THE AE REPORTING CRITERIA. Else, if this meets AE reporting criteria per protocol a corresponding AE should be recorded.' answered with 'solicited event' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 13:36:07
User opened query 'Per DM CLR RQ: Response to previous query noted. However, please confirm if this SOLICITED ADVERSE REACTION OF FEVER DID NOT MEET THE AE REPORTING CRITERIA. Else, if this meets AE reporting criteria per protocol a corresponding AE should be recorded.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:03:41

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR RQ: Response noted. However, please confirm in query response if the SOLICITED ADVERSE REACTION OF FEVER DID NOT MEET THE AE REPORTING CRITERIA. Else, if this meets AE reporting criteria per protocol a corresponding AE should be recorded or if this is related to recorded AE of covid, please update indication so there is an appropriate match.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:09:28
Query 'Per DM CLR RQ: Response noted. However, please confirm in query response if the SOLICITED ADVERSE REACTION OF FEVER DID NOT MEET THE AE REPORTING CRITERIA. Else, if this meets AE reporting criteria per protocol a corresponding AE should be recorded or if this is related to recorded AE of covid, please update indication so there is an appropriate match.' answered with 'solicited diary event' (Site from DM).	Donna Toepfer (b) (4)	23 Sep 2020 12:13:05
User opened query 'Per DM CLR RQ: Response noted. However, please confirm in query response if the SOLICITED ADVERSE REACTION OF FEVER DID NOT MEET THE AE REPORTING CRITERIA. Else, if this meets AE reporting criteria per protocol a corresponding AE should be recorded or if this is related to recorded AE of covid, please update indication so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:10:55
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 12:11:35

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria' answered with 'solicited event from diary' (Site from DM).	Donna Toepfer (b) (4)	15 Sep 2020 12:35:57
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:13:24
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
User entered 'Fever'	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User closed query 'According to source the dose for Acetaminophen is 1000 mg. Please refer to source and update entry as required.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:14:40 09 Nov 2020 17:14:07
Query 'According to source the dose for Acetaminophen is 1000 mg. Please refer to source and update entry as required.' answered with 'UPDATED' (Site from CRA). DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4) Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 17:04:05 09 Nov 2020 17:03:42
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 17:03:42
User entered '1000' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	09 Nov 2020 17:03:42
User opened query 'According to source the dose for Acetaminophen is 1000 mg. Please refer to source and update entry as required.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 16:07:23 24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '500'	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'mg (mg)'	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:56:49

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Grace Newville (b) (4)	12 Aug 2020 13:54:48
New Information	(b) (4)	
User entered 'once (ONCE)'	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '10 Aug 2020'	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '11 Aug 2020' reason for change: New Information	Grace Newville (b) (4)	12 Aug 2020 13:54:48
	(b) (4)	
User entered '10 Aug 2020'	Donna Toepfer (b) (4)	11 Aug 2020 14:56:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:31:38
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:39:47
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. Otherwise, please provide clarification.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:20:53
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:20:48
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:20:48
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:20:48
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:11:32
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
User entered empty.	System	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
User entered empty.	System	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:24
User entered empty.	System	11 Aug 2020 14:56:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 17:59:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 17:59:37
Data point term sent to Coder	System	08 Feb 2021 17:58:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:46:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:46:42
Data point term sent to Coder	System	04 Dec 2020 13:24:56
Coding entries removed.	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:24:10

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:13:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:13:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:49:06
Data point term sent to Coder	System	19 Nov 2020 16:02:33
Data point term sent to Coder	System	19 Nov 2020 15:43:55
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:43:37
Coding entries removed.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:43:37
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 15:43:37
User entered 'BACTRIM DS1' reason for change:	Erynn McKinley (b) (4)	19 Nov 2020 15:43:37
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 12:38:45
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 Sep 2020 12:38:45
Data point term sent to Coder	System	15 Sep 2020 12:38:05
Coding entries removed.	Donna Toepfer (b) (4) (b) (4)	15 Sep 2020 12:38:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:10:44
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 00:10:44
Data point term sent to Coder	System	14 Aug 2020 20:04:32
User entered 'Bactrim'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:04:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Aug 2020 20:04:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:31:38
User closed query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:40:47
Query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:24:17
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:24:10
User entered 'Covid-19' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	04 Dec 2020 13:24:10
User opened query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:12:45
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:49:06
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 16:02:08
User entered 'Upper Respiratory Infection' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 16:02:08
User closed query 'Per DM CLR-Requery: Response noted, since this is a combination drug, please ensure to update Dose field to reflect both combination doses in the dose field instead of the number of tablet. Please update both Dose and dose unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:08:14

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR-Requery: Response noted, since this is a combination drug, please ensure to update Dose field to reflect both combination doses in the dose field instead of the number of tablet. Please update both Dose and dose unit fields as appropriate. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	05 Oct 2020 13:03:12
User opened query 'Per DM CLR-Requery: Response noted, since this is a combination drug, please ensure to update Dose field to reflect both combination doses in the dose field instead of the number of tablet. Please update both Dose and dose unit fields as appropriate.	(b) (4), (b) (6)	05 Oct 2020 09:33:21
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the UPPER RESPIRATORY INFECTION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of UPPER RESPIRATORY INFECTION did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 12:13:33

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the UPPER RESPIRATORY INFECTION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of UPPER RESPIRATORY INFECTION did not meet the AE reporting criteria.' answered with 'updated' (Site from DM). Signature has been broken.	Donna Toepfer (b) (4) (b) (4) (b) (4)	15 Sep 2020 12:38:09
	Donna Toepfer (b) (4) (b) (4)	15 Sep 2020 12:38:04
User entered 'COVID-19' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	15 Sep 2020 12:38:04
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the UPPER RESPIRATORY INFECTION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of UPPER RESPIRATORY INFECTION did not meet the AE reporting criteria.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4) Nathan Segall (b) (4) (b) (4)	15 Sep 2020 12:14:08 31 Aug 2020 13:42:38
User entered 'Upper respiratory infection'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:04:06

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:44
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:08:16
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
User entered '160/800' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'this is actual dose, combination drug.' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	15 Sep 2020 12:37:42
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:14:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '1'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:04:06

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:44
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
User entered 'mg (mg)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'tablet (TABLET)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:04:06

US3242002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	14 Aug 2020 20:04:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	14 Aug 2020 20:04:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	14 Aug 2020 20:04:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	14 Aug 2020 20:04:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:04:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	14 Aug 2020 20:04:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered '0'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:04:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:44
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:08:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:03:21
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:33:32
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:04:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:44
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
User entered '19 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	05 Oct 2020 13:02:54
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:42:38
User entered empty.	Donna Toepfer (b) (4) (b) (4)	14 Aug 2020 20:04:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 16:02:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Aug 2020 20:04:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User entered '1'	System	14 Aug 2020 20:04:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User entered '1'	System	14 Aug 2020 20:04:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:24:30
User entered '804 (804)'	System	14 Aug 2020 20:04:06

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:06:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 16:10:14
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'Visit 2 Day 29 (VISIT2)'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

Central Laboratory - Nasopharyngeal Swab

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '1 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 16:03:44
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User closed query 'Category is not checked Other, however specify has been provided. Please correct.' (Site from System).	System	19 Oct 2020 16:03:44
Query 'Category is not checked Other, however specify has been provided. Please correct.' answered by data change (Site from System).	System	19 Oct 2020 16:03:44
User opened query 'Category is not checked Other, however specify has been provided. Please correct.' (Site from System).	System	19 Oct 2020 16:02:53
User entered 'PC D36, D43, D50 were affected.'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4) (b) (4)	19 Oct 2020 16:02:53

US3242002

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:06:10

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:26:11
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:19
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 16:02:53
	(b) (4)	

US3242002

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:06:10

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:54
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '26 Aug 2020'	Donna Toepfer (b) (4)	27 Aug 2020 12:50:55
	(b) (4)	

US3242002

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:06:10

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:54
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'Due to SARS-COV-2 (COVID)'	Donna Toepfer (b) (4)	27 Aug 2020 12:50:55
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:06:10

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:54
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 12:50:55
	(b) (4)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered		
'USA-US067-2020-MRNA-1273-P301000001'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Nathan'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Segall'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered '175 country club dr st100a'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Stockbridge'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered '30281'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 18:45:53
User entered 'US' (non-conformant).	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Signature has been broken.	System	03 Sep 2020 01:16:34
User entered '3'	System	03 Sep 2020 01:16:34
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '2'	System	26 Aug 2020 18:46:15
User entered '1'	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered	System	20 Aug 2020 14:20:46
'USA-US067-2020-MRNA-1273-P301000001'		

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Nathan'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Segall'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered '175 country club dr st100a'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Stockbridge'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered '30281'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 18:45:53
User entered 'US' (non-conformant).	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Signature has been broken.	System	03 Sep 2020 01:16:34
User entered '3'	System	03 Sep 2020 01:16:34
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '2'	System	26 Aug 2020 18:46:15
User entered '1'	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:06:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '20/Aug/2020 10:29'	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:06:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 18:45:53
User entered 'I'	(b) (4), (b) (6)	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered		
'USA-US067-2020-MRNA-1273-P301000001'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Nathan'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Segall'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered '175 country club dr st100a'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Stockbridge'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered '30281'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 18:45:53
User entered 'US' (non-conformant).	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Signature has been broken.	System	03 Sep 2020 01:16:34
User entered '3'	System	03 Sep 2020 01:16:34
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '2'	System	26 Aug 2020 18:46:15
User entered '1'	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:06:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '26/Aug/2020 14:46'	System	26 Aug 2020 18:46:15

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:06:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	26 Aug 2020 18:46:15

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered		
'USA-US067-2020-MRNA-1273-P301000001'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Aug 2020 14:29:12
User entered 'No (N)'	System	20 Aug 2020 14:20:46

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Nathan'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Segall'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered '175 country club dr st100a'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered 'Stockbridge'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
Amendment Manager: User entered '30281'	System	14 Sep 2020 21:44:50

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
	(b) (4), (b) (6)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:55:06
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 18:45:53
User entered 'US' (non-conformant).	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 17:58:37
	(b) (4)	
Signature has been broken.	System	03 Sep 2020 01:16:34
User entered '3'	System	03 Sep 2020 01:16:34
User signature succeeded.	Nathan Segall (b) (4)	31 Aug 2020 13:42:38
	(b) (4)	
User entered '2'	System	26 Aug 2020 18:46:15
User entered '1'	System	20 Aug 2020 14:29:26

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:06:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
User entered '02/Sep/2020 21:16'	System	03 Sep 2020 01:16:34

US3242002

Folder: SAE USA-US067-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:06:10

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.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 17:58:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:18:49
User entered 'I'	(b) (4), (b) (6)	03 Sep 2020 01:16:34