

US3112266 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:52:04

All time stamps listed in this document are displayed in GMT

US3112266

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:21:39

Generated On: 11 Aug 2021 21:52:04

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Participant ID

US3112266

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

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US3112266

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:04:47

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 17:04:46

Generated On: 11 Aug 2021 21:52:04

Date of Birth (MMM yyyy)	(b) (6) 1992
Age	28
Age Units	YEARS
Age (Derived)	28
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3112266

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 17:04:46

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 17:04:46

Generated On: 11 Aug 2021 21:52:04

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3112266

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 17:04:46

Generated On: 11 Aug 2021 21:52:04

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Were any significant conditions reported?

Yes ☒

No ☐

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US3112266

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 17:04:46

Generated On: 11 Aug 2021 21:52:04

Condition	MIGRAINES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



US3112266

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:04:47

Generated On: 11 Aug 2021 21:52:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:36
Height (xxx.x)	74 in
Weight (xxx.x)	233 lb
BMI (xxx.x)	29.97798 kg/m <sup>2</sup>
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)	

US3112266

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:04:46

Generated On: 11 Aug 2021 21:52:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3112266

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:04:46

Generated On: 11 Aug 2021 21:52:04

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify** CONSULT

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

US3112266

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:04:46

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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

Visit date (dd MMM yyyy)	14 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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US3112266

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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

What was the participant's randomization number? 104532

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Height	ND - Not Done
Weight	ND - Not Done

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:36
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG



US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 14:43
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3112266

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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.*

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:12 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 14:12

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

US3112266

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

14 AUG 2020 13:40

US3112266

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:26	14 AUG 2020 13:26
Nasopharyngeal Swab 2	No		

US3112266

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:43

PC Open Date & Time

14 AUG 2020 14:32

PC Close Date & Time

14 AUG 2020 17:02

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	14 AUG 2020 19:51
PC Open Date & Time	14 AUG 2020 17:57
PC Close Date & Time	15 AUG 2020 11:59



US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

15 AUG 2020 13:04

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:04

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**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.

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.6 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

16 AUG 2020 13:19

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PC Open Date & Time

16 AUG 2020 12:00

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PC Close Date & Time

17 AUG 2020 11:59

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US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 18:56

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:04

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 12:04

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 12:14

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:00

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 14:44

PC Open Date & Time

14 AUG 2020 14:32

PC Close Date & Time

14 AUG 2020 17:02

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 19:52

PC Open Date & Time

14 AUG 2020 17:57

PC Close Date & Time

15 AUG 2020 11:59



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:08

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:04

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:04

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 12:13

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 12:00

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**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 ☐

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 14:44
PC Open Date & Time	14 AUG 2020 14:32
PC Close Date & Time	14 AUG 2020 17:02



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**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 ☐

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 19:52
PC Open Date & Time	14 AUG 2020 17:57
PC Close Date & Time	15 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

42 of 2210

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:08
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

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 ☒

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:04
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

46 of 2210

EAB) (1725)

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:03
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 2210

EAB) (1725)

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

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 ☒

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:13
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

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 ☒

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:48:27

Generated On: 11 Aug 2021 21:52:04

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*

US3112266

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:48:27

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112266

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:48:26

Generated On: 11 Aug 2021 21:52:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112266

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:48:26

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:48:27

Generated On: 11 Aug 2021 21:52:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112266

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:48:27

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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.*



US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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?

US3112266

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3112266

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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	No		
Nasopharyngeal Swab 2	No		

US3112266

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:48:27

Generated On: 11 Aug 2021 21:52:04

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

PATIENT IN CONVALESCENT  
PHASE

If Contact Not Made, please provide Comments

US3112266

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:48:27

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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

PATIENT IN CONVALESCENT  
PHASE

*If Contact Not Made, please provide Comments*

US3112266

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112266

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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

PATIENT IN CONVALESCENT  
PHASE

If Contact Not Made, please provide Comments

US3112266

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

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 VISIT3

US3112266

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:13:22

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 OCT 2020 18:14:53
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	21 OCT 2020 21:32:26
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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	28 OCT 2020 12:29:45
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 10:39:01

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59



US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☒

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

18 NOV 2020 09:15:16

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 11:00:06

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 15:45:23

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 09:04:54

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 00:01:30
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 00:03:12

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 00:01:23

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 00:05:52

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59



US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 14:33:16

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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	17 JAN 2021 00:01:25
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 00:12:01
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 00:01:39

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 14:06:18
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 00:42:47

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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

21 FEB 2021 00:12:38

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 08:01:40

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59



US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

<b>TIMEPOINT</b>	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 09:09:30
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 00:02:21

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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

24 MAR 2021 15:20:23

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

<b>TIMEPOINT</b>	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	28 MAR 2021 09:44:25
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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

06 APR 2021 12:00:20

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 09:53:38

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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

18 APR 2021 00:02:39

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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

25 APR 2021 00:08:30

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59



US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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

02 MAY 2021 00:16:05

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐ 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 ☐



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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06 JAN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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°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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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20 JAN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐ 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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

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30 JAN 2022 00:01

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03 FEB 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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°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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

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03 MAR 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 656

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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°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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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="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"/>



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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14 JUL 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 705

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

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17 JUL 2022 00:01

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21 JUL 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**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 ☐



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

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11 AUG 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

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14 AUG 2022 00:01

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18 AUG 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

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28 AUG 2022 00:01

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01 SEP 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

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04 SEP 2022 00:01

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08 SEP 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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="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"/>

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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"/>



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3112266

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:52:04

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		28 FEB 2021 08:01:32

US3112266

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:53:51

Generated On: 11 Aug 2021 21:52:04

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

CONTACT INADVERTENTLY  
MISSED.

If Contact Not Made, please provide Comments

US3112266

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:53:51

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112266

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112266

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112266

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112266

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:44

Generated On: 11 Aug 2021 21:52:04

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

Visit date (dd MMM yyyy)	19 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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US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:21:44

Generated On: 11 Aug 2021 21:52:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	08:39 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 08:39
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112266

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:44

Generated On: 11 Aug 2021 21:52:04

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.*

US3112266

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:44

Generated On: 11 Aug 2021 21:52:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

09:05 (24 HR)

Collection date and time (derived)

19 MAR 2021 09:05

US3112266

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 23:37:27

Generated On: 11 Aug 2021 21:52:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3112266

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 23:37:27

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

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*

**US3112266**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:04**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Date of Contact 10 SEP 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☐

Safety Call ☒

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2? Yes ☒

No ☐

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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)

277 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

278 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

Date	16 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

285 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

Date	17 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

289 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

Date	18 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

293 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

294 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

Date	20 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

301 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

Date	21 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

305 of 2210

EAB) (1725)

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

309 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

313 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

317 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

318 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

321 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Symptom Day

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

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

325 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Symptom Day

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

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

329 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

333 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

334 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

337 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

341 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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

Date	10 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

345 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

349 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

353 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

	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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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"/>

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Date of Visit	13 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	13 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

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)

357 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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)

358 of 2210

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

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



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 SEP 2020
Day 5	Yes	17 SEP 2020
Day 7	Yes	19 SEP 2020
Day 9	Yes	21 SEP 2020
Day 14	Yes	26 SEP 2020
Day 21	Yes	03 OCT 2020
Day 28	Yes	10 OCT 2020

US3112266

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

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

Visit date (dd MMM yyyy)	13 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>

Folder OID	SICKD1
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US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:17 (24 HR)
Vital Signs Date and Time (derived)	13 SEP 2020 10:17
Height ( <i>xxx.x</i> )	ND - Not Done
Weight ( <i>xxx.x</i> )	ND - Not Done
Temperature ( <i>xxx.x</i> )	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112266

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 SEP 2020

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

US3112266

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 SEP 2020

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD28

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 OCT 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	10 OCT 2020 08:20
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 OCT 2020

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

US3112266

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 OCT 2020

US3112266

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

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

Visit date (dd MMM yyyy)	16 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>

Folder OID	UNBLND_DECIDE
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US3112266

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Date of updated informed consent ( <i>dd MMM yyyy</i> )	6 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> )	16 FEB 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

US3112266

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

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

US3112266

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

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)	16 FEB 2021
Time of assessment (00:00-23:59)	08:49 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 08:49
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3112266

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

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)	16 FEB 2021
Time of assessment (00:00-23:59)	09:54 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 09:54
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3112266

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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



US3112266

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 16 FEB 2021

What was the treatment time? (00:00-23:59) 09:23 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 09:23

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

US3112266

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

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

Collection date (dd MMM yyyy)	16 FEB 2021
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Collection time (00:00-23:59)	9:00 (24 HR)
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Collection date and time (derived)	16 FEB 2021 9:00
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US3112266

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 FEB 2021
Collection time (00:00 - 23:59)	08:53
Collection Date and Time (derived)	16 FEB 2021 08:53

US3112266

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112266

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

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

US3112266

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

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

Visit date (dd MMM yyyy)	19 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	OLD29
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US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	08:29 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 08:29
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

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)	19 MAR 2021
Time of assessment (00:00-23:59)	09:43 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 09:43
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3112266

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

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.*

US3112266

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

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) 19 MAR 2021

What was the treatment time? (00:00-23:59) 09:12 (24 HR)

Treatment Date and Time (derived) 19 MAR 2021 09:12

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

US3112266

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112266

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3112266

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3112266**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:04**

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 \_\_\_\_\_

US3112266

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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



US3112266

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

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.*

US3112266

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3112266

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:27:56

Generated On: 11 Aug 2021 21:52:04

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:27:56

Generated On: 11 Aug 2021 21:52:04

AEID	USA-US062-2020-MRNA-1273-P30 1000004
Adverse event	COVID 19 DIAGNOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	06 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

395 of 2210

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:27:56

Generated On: 11 Aug 2021 21:52:04

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

---

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

Yes ☒

No ☐

---

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

---

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:21:39

Generated On: 11 Aug 2021 21:52:04

Name of Medication EXCEDRIN MIGRAINE

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE/HEADACHE

Dose per administration 250/65

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)

398 of 2210

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:21:39

Generated On: 11 Aug 2021 21:52:04

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



US3112266

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:21:40

Generated On: 11 Aug 2021 21:52:04

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3112266

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Date of dosing discontinuation (dd MMM yyyy) 13 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3112266

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 02 Apr 2021 21:21:42

Generated On: 11 Aug 2021 21:52:04

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

SAEID	USA-US062-2020-MRNA-1273-P301000004
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

SAEID	USA-US062-2020-MRNA-1273-P301000004
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/OCT/2020 13:49
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

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

SAEID	USA-US062-2020-MRNA-1273-P301000004
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	27/OCT/2020 13:21
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

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:21:43

Generated On: 11 Aug 2021 21:52:04

SAEID	USA-US062-2020-MRNA-1273-P301000004
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/NOV/2020 15:46
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

Audit

US3112266 (Prod: Medical Center For Clinical Research - M3 Wake Research)



US3112266

Form: Participant Creation

Generated On: 11 Aug 2021 21:52:04

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'US3112266'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 20:19:21

US3112266

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:35

US3112266

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 20:19:22

US3112266

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Clinic (Clinic)'	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:35

**US3112266**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:04**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'SCRN'	System	14 Aug 2020 21:23:35

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered (b) (6) 1992'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 20:19:23

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:31:13
Query 'Per CDM: Please complete this form.' answered with 'This is completed.' (Site from DM).	(b) (4), (b) (6)	21 Aug 2020 19:17:13
User entered '28'	(b) (4), (b) (6)	21 Aug 2020 19:17:07
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 15:59:06

**US3112266**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:04**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'YEARS'	System	21 Aug 2020 19:17:07



**US3112266**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:04**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered '28'	System	14 Aug 2020 21:23:50

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07



US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:04

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:07

US3112266

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '14 Aug 2020'	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:50

US3112266

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'Aug 2020'	System	14 Aug 2020 21:23:50

**US3112266**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered '2020'	System	14 Aug 2020 21:23:50

US3112266

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:04

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Amendment 2 (2)'	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:50



US3112266

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:50

US3112266

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty.	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:50

US3112266

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty.	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:50

US3112266

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 21:23:54
User entered 'No (N)' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 21:23:50
User entered empty.	Nicolle Mendez (b) (4)	14 Aug 2020 21:23:50
	(b) (4)	

US3112266

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 20:19:22

**US3112266**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:04**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'I'	System	14 Aug 2020 21:24:00

US3112266

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	14 Aug 2020 21:24:00

US3112266

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:52:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User closed query 'Per source illness visit 9/18/2020 indicates history of migraine headache. Please confirm and update as necessary.' (Site from CRA).	(b) (4)	
Query 'Per source illness visit 9/18/2020 indicates history of migraine headache. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:20:19
Matthew Musikanth		
Query 'Per source illness visit 9/18/2020 indicates history of migraine headache. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	(b) (4)	30 Oct 2020 18:48:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth	30 Oct 2020 18:47:56
	(b) (4)	
User opened query 'Per source illness visit 9/18/2020 indicates history of migraine headache. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 23:44:02
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:20:38



US3112266

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 18:48:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 18:48:56
Data point term sent to Coder	System	30 Oct 2020 18:48:44
User entered 'Migraines'	Matthew Musikanth	30 Oct 2020 18:48:10
	(b) (4)	

US3112266

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty.	(b) (4) Matthew Musikanth	30 Oct 2020 18:48:10
	(b) (4)	

US3112266

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'I'	Matthew Musikanth (b) (4)	30 Oct 2020 18:48:10

US3112266

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 18:48:16
User entered 'Yes (Y)' reason for change: Data Entry Error	System	30 Oct 2020 18:48:16
User opened query 'Data is required. Please complete.' (Site from System).	Matthew Musikanth	30 Oct 2020 18:48:16
User entered empty.	(b) (4)	
	System	30 Oct 2020 18:48:10
	Matthew Musikanth	30 Oct 2020 18:48:10
	(b) (4)	

US3112266

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty.	(b) (4) Matthew Musikanth	30 Oct 2020 18:48:10
	(b) (4)	

US3112266

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	30 Oct 2020 18:48:10

**US3112266**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered empty.	System	30 Oct 2020 18:48:10

**US3112266**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered empty.	System	30 Oct 2020 18:48:10



**US3112266**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered empty.	System	30 Oct 2020 18:48:10

**US3112266**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered empty.	System	30 Oct 2020 18:48:10

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:18:35

**US3112266**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '13:36'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered '14 Aug 2020 13:36'	System	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '74' in	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:18:35
DataPoint set to visible.	System	14 Aug 2020 21:24:00

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '233' lb	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:18:35
DataPoint set to visible.	System	14 Aug 2020 21:24:00



US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
Amendment Manager: User entered '29.97798'	System	16 Sep 2020 23:58:04
User entered '30.0'	System	21 Aug 2020 19:18:35
DataPoint set to visible.	System	14 Aug 2020 21:24:00

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'kg/m2'	System	21 Aug 2020 19:18:35
DataPoint set to visible.	System	14 Aug 2020 21:24:00

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 03:41:17
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' answered with 'Updated ' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 02:30:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 02:30:00
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 19:20:28
User entered '98.5' F	(b) (4), (b) (6)	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	06 Sep 2020 02:30:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 02:30:00
User entered '66'	(b) (4), (b) (6)	21 Aug 2020 19:18:35

**US3112266**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:04**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'bpm'	System	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 02:30:00
User entered '14'	(b) (4), (b) (6)	21 Aug 2020 19:18:35



US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'breaths/min'	System	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 02:30:00
User entered '117'	(b) (4), (b) (6)	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'mmHg'	System	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Sep 2020 02:30:00
User entered '56'	(b) (4), (b) (6)	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User entered 'mmHg'	System	21 Aug 2020 19:18:35

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 13:08:05

US3112266

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05

US3112266

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:29



US3112266

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:29

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57



US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'Consult'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57



US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

**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 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:08:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:57

US3112266

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4)	14 Aug 2020 21:23:22
	Nicolle Mendez (b) (4)	
	(b) (4)	

US3112266

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14 Aug 2020'	(b) (4)	14 Aug 2020 21:23:22
	Nicolle Mendez (b) (4)	
	(b) (4)	



US3112266

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Clinic (Clinic)'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	14 Aug 2020 21:23:22

US3112266

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'VISIT1'	System	14 Aug 2020 21:23:22

US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 20:39:16

US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 04:42:37
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:42:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 20:39:16
User entered '104532' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 20:39:16

US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 20:39:16

US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:23

US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:23

US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:23



US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:23

US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:17:23

US3112266

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:04

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 12:58:33
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	04 Nov 2020 16:49:12
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	04 Nov 2020 16:49:02
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:53:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:24:51

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 19:19:28



US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '13:36'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered '14 Aug 2020 13:36'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '66'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28



US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'bpm'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'breaths/min'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '117'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'mmHg'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:38:25
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 20:26:49
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:58:04
User entered '56'	(b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'mmHg'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28



US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14:43'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered '14 Aug 2020 14:43'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28



US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '64'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'bpm'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'breaths/min'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '122'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'mmHg'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:38:32
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 20:26:54
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:58:04
User entered '54'	(b) (4), (b) (6)	21 Aug 2020 19:19:28



US3112266

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'mmHg'	System	21 Aug 2020 19:19:28

US3112266

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:13

US3112266

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:13

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4)	14 Aug 2020 21:24:36
	(b) (4)	

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4)	14 Aug 2020 21:24:36
	Nicolle Mendez (b) (4)	
	(b) (4)	

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4)	14 Aug 2020 21:24:36
	Nicolle Mendez (b) (4)	
	(b) (4)	

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 21:24:36

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14 Aug 2020'	(b) (4) Nicolle Mendez (b) (4)	14 Aug 2020 21:24:36
	(b) (4)	



US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14:12'	(b) (4) Nicolle Mendez (b) (4)	14 Aug 2020 21:24:36
	(b) (4)	

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered '14 Aug 2020 14:12'	System	14 Aug 2020 21:24:36

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	14 Aug 2020 21:24:36

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'ONCE'	System	14 Aug 2020 21:24:36

US3112266

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 21:24:36

US3112266

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:50

US3112266

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:50

US3112266

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '13:40'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:19:50



US3112266

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered '14 Aug 2020 13:40'	System	21 Aug 2020 19:19:50

US3112266

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:52:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:06

US3112266

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 19:20:06

US3112266

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:06

US3112266

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered '13:26'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:06

**US3112266**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered '14 Aug 2020 13:26'	System	21 Aug 2020 19:20:06

US3112266

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 19:20:06

US3112266

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:06



US3112266

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:06

**US3112266**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	21 Aug 2020 19:20:06

US3112266

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:20:34

US3112266

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'I'	System	21 Aug 2020 19:20:34

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:42:45', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3cf807b3-108b-4531-84e6-4b8f6409742d' User entered 'Yes (Y)'	System	14 Aug 2020 21:43:21
	System	14 Aug 2020 21:43:21

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:43:11', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3cf807b3-108b-4531-84e6-4b8f6409742d' User entered '98.4'	System	14 Aug 2020 21:43:21
	System	14 Aug 2020 21:43:21

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:43:15', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3cf807b3-108b-4531-84e6-4b8f6409742d' User entered 'No (N)'	System	14 Aug 2020 21:43:21
	System	14 Aug 2020 21:43:21



US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:43:20', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3cf807b3-108b-4531-84e6-4b8f6409742d' User entered '14 Aug 2020 14:43'	System	14 Aug 2020 21:43:21
	System	14 Aug 2020 21:43:21

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 14:32'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 17:02'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:51:05', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4bd2fbc2-c11e-463b-9b3d-483d7d81de2f' User entered 'Yes (Y)'	System	15 Aug 2020 02:51:53
	System	15 Aug 2020 02:51:53

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:51:43', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4bd2fbc2-c11e-463b-9b3d-483d7d81de2f' User entered '98.6'	System	15 Aug 2020 02:51:53
	System	15 Aug 2020 02:51:53

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:51:46', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4bd2fbc2-c11e-463b-9b3d-483d7d81de2f' User entered 'No (N)'	System	15 Aug 2020 02:51:53
	System	15 Aug 2020 02:51:53

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:51:49', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4bd2fbc2-c11e-463b-9b3d-483d7d81de2f' User entered '14 Aug 2020 19:51'	System	15 Aug 2020 02:51:53
	System	15 Aug 2020 02:51:53



US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 17:57'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 2'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T13:04:48', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '70ad2b78-5b87-40a9-b25a-84667065f211'	System	15 Aug 2020 20:05:01
User entered 'Yes (Y)'	System	15 Aug 2020 20:05:01

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T13:04:52', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '70ad2b78-5b87-40a9-b25a-84667065f211' User entered '98.2'	System	15 Aug 2020 20:05:01
	System	15 Aug 2020 20:05:01

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T13:04:55', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '70ad2b78-5b87-40a9-b25a-84667065f211'	System	15 Aug 2020 20:05:01
User entered 'No (N)'	System	15 Aug 2020 20:05:01

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T13:04:59', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '70ad2b78-5b87-40a9-b25a-84667065f211' User entered '15 Aug 2020 13:04'	System	15 Aug 2020 20:05:01
	System	15 Aug 2020 20:05:01

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 21:24:36



US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 3'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T13:19:15', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6b51de34-83f2-4576-ad9e-dd1fe7a32aa3'	System	16 Aug 2020 20:19:26
User entered 'Yes (Y)'	System	16 Aug 2020 20:19:26

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T13:19:19', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6b51de34-83f2-4576-ad9e-dd1fe7a32aa3' User entered '98.6'	System	16 Aug 2020 20:19:26
	System	16 Aug 2020 20:19:26

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T13:19:21', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6b51de34-83f2-4576-ad9e-dd1fe7a32aa3'	System	16 Aug 2020 20:19:26
User entered 'No (N)'	System	16 Aug 2020 20:19:26

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T13:19:23', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6b51de34-83f2-4576-ad9e-dd1fe7a32aa3'	System	16 Aug 2020 20:19:26
User entered '16 Aug 2020 13:19'	System	16 Aug 2020 20:19:26

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 21:24:36



US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 4'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T18:56:51', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '523e72e9-85e0-4804-b7f0-3c930052f4ec' User entered 'Yes (Y)'	System	18 Aug 2020 01:57:02
	System	18 Aug 2020 01:57:02

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T18:56:54', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '523e72e9-85e0-4804-b7f0-3c930052f4ec' User entered '98.6'	System	18 Aug 2020 01:57:02
	System	18 Aug 2020 01:57:02

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T18:56:57', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '523e72e9-85e0-4804-b7f0-3c930052f4ec'	System	18 Aug 2020 01:57:02
User entered 'No (N)'	System	18 Aug 2020 01:57:02

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T18:56:59', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '523e72e9-85e0-4804-b7f0-3c930052f4ec' User entered '17 Aug 2020 18:56'	System	18 Aug 2020 01:57:02
	System	18 Aug 2020 01:57:02

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 5'	System	14 Aug 2020 21:24:36



US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:04:07', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '9842c380-0a38-4564-b779-3f21eb47671b' User entered 'Yes (Y)'	System	18 Aug 2020 19:04:22
	System	18 Aug 2020 19:04:22

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:04:11', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '9842c380-0a38-4564-b779-3f21eb47671b' User entered '98.6'	System	18 Aug 2020 19:04:22
	System	18 Aug 2020 19:04:22

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:04:13', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '9842c380-0a38-4564-b779-3f21eb47671b' User entered 'No (N)'	System	18 Aug 2020 19:04:22
	System	18 Aug 2020 19:04:22

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:04:18', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '9842c380-0a38-4564-b779-3f21eb47671b' User entered '18 Aug 2020 12:04'	System	18 Aug 2020 19:04:22
	System	18 Aug 2020 19:04:22

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 6'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:14:04', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3834dc01-5b6f-48ce-87da-645a875726f4' User entered 'Yes (Y)'	System	19 Aug 2020 19:14:14
	System	19 Aug 2020 19:14:14



US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:14:07', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3834dc01-5b6f-48ce-87da-645a875726f4' User entered '98.6'	System	19 Aug 2020 19:14:14
	System	19 Aug 2020 19:14:14

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:14:10', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3834dc01-5b6f-48ce-87da-645a875726f4'	System	19 Aug 2020 19:14:14
User entered 'No (N)'	System	19 Aug 2020 19:14:14

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:14:11', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3834dc01-5b6f-48ce-87da-645a875726f4' User entered '19 Aug 2020 12:14'	System	19 Aug 2020 19:14:14
	System	19 Aug 2020 19:14:14

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 7'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:12', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '9f455ff5-b9ae-42b9-86fb-a29a86fb855a' User entered 'Yes (Y)'	System	20 Aug 2020 19:00:26
	System	20 Aug 2020 19:00:26

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:16', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '9f455ff5-b9ae-42b9-86fb-a29a86fb855a' User entered '97.8'	System	20 Aug 2020 19:00:26
	System	20 Aug 2020 19:00:26



US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:20', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '9f455ff5-b9ae-42b9-86fb-a29a86fb855a'	System	20 Aug 2020 19:00:26
User entered 'No (N)'	System	20 Aug 2020 19:00:26

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:22', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '9f455ff5-b9ae-42b9-86fb-a29a86fb855a'	System	20 Aug 2020 19:00:26
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 19:00:26

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:43:36', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1d6bfc88-ade0-4441-9d0e-2bd26bcf8c7a'	System	14 Aug 2020 21:44:21
User entered 'None (1)'	System	14 Aug 2020 21:44:21

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:43:45', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1d6bfc88-ade0-4441-9d0e-2bd26bcf8c7a' User entered 'No (N)'	System	14 Aug 2020 21:44:21
	System	14 Aug 2020 21:44:21

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:43:48', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1d6bfc88-ade0-4441-9d0e-2bd26bcf8c7a' User entered 'No (N)'	System	14 Aug 2020 21:44:21
	System	14 Aug 2020 21:44:21



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:02', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1d6bfc88-ade0-4441-9d0e-2bd26bcf8c7a' User entered 'None (1)'	System	14 Aug 2020 21:44:21
	System	14 Aug 2020 21:44:21

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:06', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1d6bfc88-ade0-4441-9d0e-2bd26bcf8c7a' User entered '14 Aug 2020 14:44'	System	14 Aug 2020 21:44:21
	System	14 Aug 2020 21:44:21

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 14:32'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 17:02'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:51:52', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3eef7c9b-db37-4cd5-bfe2-11c184dc104c' User entered 'None (1)'	System	15 Aug 2020 02:52:14
	System	15 Aug 2020 02:52:14

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:04', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3eef7c9b-db37-4cd5-bfe2-11c184dc104c' User entered 'No (N)'	System	15 Aug 2020 02:52:14
	System	15 Aug 2020 02:52:14

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:08', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3eef7c9b-db37-4cd5-bfe2-11c184dc104c' User entered 'No (N)'	System	15 Aug 2020 02:52:14
	System	15 Aug 2020 02:52:14



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:10', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3eef7c9b-db37-4cd5-bfe2-11c184dc104c' User entered 'None (1)'	System	15 Aug 2020 02:52:14
	System	15 Aug 2020 02:52:14

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:12', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '3eef7c9b-db37-4cd5-bfe2-11c184dc104c' User entered '14 Aug 2020 19:52'	System	15 Aug 2020 02:52:14
	System	15 Aug 2020 02:52:14

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 17:57'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 2'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:05', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'cef68dbc-2bb8-4bc9-b85c-1b710b4ee66b' User entered 'None (1)'	System	15 Aug 2020 19:08:45
	System	15 Aug 2020 19:08:45

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:11', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'cef68dbc-2bb8-4bc9-b85c-1b710b4ee66b'	System	15 Aug 2020 19:08:45
User entered 'No (N)'	System	15 Aug 2020 19:08:45

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:21', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'cef68dbc-2bb8-4bc9-b85c-1b710b4ee66b'	System	15 Aug 2020 19:08:45
User entered 'No (N)'	System	15 Aug 2020 19:08:45



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:23', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'cef68dbc-2bb8-4bc9-b85c-1b710b4ee66b' User entered 'None (1)'	System	15 Aug 2020 19:08:45
	System	15 Aug 2020 19:08:45

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:30', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'cef68dbc-2bb8-4bc9-b85c-1b710b4ee66b'	System	15 Aug 2020 19:08:45
User entered '15 Aug 2020 12:08'	System	15 Aug 2020 19:08:45

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 3'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:03:54', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0382b38f-26b7-488d-9011-cde61e928959'	System	16 Aug 2020 19:04:02
User entered 'None (1)'	System	16 Aug 2020 19:04:02

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:03:56', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0382b38f-26b7-488d-9011-cde61e928959'	System	16 Aug 2020 19:04:02
User entered 'No (N)'	System	16 Aug 2020 19:04:02

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:03:58', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0382b38f-26b7-488d-9011-cde61e928959' User entered 'No (N)'	System	16 Aug 2020 19:04:02
	System	16 Aug 2020 19:04:02



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:03:59', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0382b38f-26b7-488d-9011-cde61e928959' User entered 'None (1)'	System	16 Aug 2020 19:04:02
	System	16 Aug 2020 19:04:02

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:01', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0382b38f-26b7-488d-9011-cde61e928959' User entered '16 Aug 2020 12:04'	System	16 Aug 2020 19:04:02
	System	16 Aug 2020 19:04:02

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 4'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:56', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'da9b6801-0f67-4f93-aa41-062948e7ddee'	System	17 Aug 2020 19:04:09
User entered 'None (1)'	System	17 Aug 2020 19:04:09

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:58', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'da9b6801-0f67-4f93-aa41-062948e7ddee'	System	17 Aug 2020 19:04:09
User entered 'No (N)'	System	17 Aug 2020 19:04:09

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:59', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'da9b6801-0f67-4f93-aa41-062948e7ddee'	System	17 Aug 2020 19:04:09
User entered 'No (N)'	System	17 Aug 2020 19:04:09



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:04:01', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'da9b6801-0f67-4f93-aa41-062948e7ddee'	System	17 Aug 2020 19:04:09
User entered 'None (1)'	System	17 Aug 2020 19:04:09

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:04:03', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'da9b6801-0f67-4f93-aa41-062948e7ddee'	System	17 Aug 2020 19:04:09
User entered '17 Aug 2020 12:04'	System	17 Aug 2020 19:04:09

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 5'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:00:48', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fb28ce27-8172-4867-8ec1-a4d73d398c5d' User entered 'None (1)'	System	18 Aug 2020 19:01:13
	System	18 Aug 2020 19:01:13

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:02', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fb28ce27-8172-4867-8ec1-a4d73d398c5d' User entered 'No (N)'	System	18 Aug 2020 19:01:13
	System	18 Aug 2020 19:01:13

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:04', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fb28ce27-8172-4867-8ec1-a4d73d398c5d' User entered 'No (N)'	System	18 Aug 2020 19:01:13
	System	18 Aug 2020 19:01:13



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:05', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fb28ce27-8172-4867-8ec1-a4d73d398c5d' User entered 'None (1)'	System	18 Aug 2020 19:01:13
	System	18 Aug 2020 19:01:13

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:11', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fb28ce27-8172-4867-8ec1-a4d73d398c5d' User entered '18 Aug 2020 12:01'	System	18 Aug 2020 19:01:13
	System	18 Aug 2020 19:01:13

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 6'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:37', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4e4af9b7-f585-42ad-ae81-28d92f8707e4'	System	19 Aug 2020 19:13:47
User entered 'None (1)'	System	19 Aug 2020 19:13:47

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:39', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4e4af9b7-f585-42ad-ae81-28d92f8707e4' User entered 'No (N)'	System	19 Aug 2020 19:13:47
	System	19 Aug 2020 19:13:47

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:40', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4e4af9b7-f585-42ad-ae81-28d92f8707e4' User entered 'No (N)'	System	19 Aug 2020 19:13:47
	System	19 Aug 2020 19:13:47



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:42', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4e4af9b7-f585-42ad-ae81-28d92f8707e4'	System	19 Aug 2020 19:13:47
User entered 'None (1)'	System	19 Aug 2020 19:13:47

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:43', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4e4af9b7-f585-42ad-ae81-28d92f8707e4' User entered '19 Aug 2020 12:13'	System	19 Aug 2020 19:13:47
	System	19 Aug 2020 19:13:47

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 7'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:25', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '973e0111-9e87-4ce2-bb7a-e5f97575d4bf' User entered 'None (1)'	System	20 Aug 2020 19:00:37
	System	20 Aug 2020 19:00:37

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:28', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '973e0111-9e87-4ce2-bb7a-e5f97575d4bf' User entered 'No (N)'	System	20 Aug 2020 19:00:37
	System	20 Aug 2020 19:00:37

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:29', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '973e0111-9e87-4ce2-bb7a-e5f97575d4bf' User entered 'No (N)'	System	20 Aug 2020 19:00:37
	System	20 Aug 2020 19:00:37



US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:30', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '973e0111-9e87-4ce2-bb7a-e5f97575d4bf' User entered 'None (1)'	System	20 Aug 2020 19:00:37
	System	20 Aug 2020 19:00:37

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:32', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '973e0111-9e87-4ce2-bb7a-e5f97575d4bf' User entered '20 Aug 2020 12:00'	System	20 Aug 2020 19:00:37
	System	20 Aug 2020 19:00:37

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:12', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8ba7c1b2-8d38-4939-bfd6-d379f27b3a86' User entered 'None (0)'	System	14 Aug 2020 21:44:47
	System	14 Aug 2020 21:44:47

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:17', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8ba7c1b2-8d38-4939-bfd6-d379f27b3a86' User entered 'None (0)'	System	14 Aug 2020 21:44:47
	System	14 Aug 2020 21:44:47

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:20', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8ba7c1b2-8d38-4939-bfd6-d379f27b3a86' User entered 'None (0)'	System	14 Aug 2020 21:44:47
	System	14 Aug 2020 21:44:47



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:27', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8ba7c1b2-8d38-4939-bfd6-d379f27b3a86' User entered 'None (0)'	System	14 Aug 2020 21:44:47
	System	14 Aug 2020 21:44:47

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:32', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8ba7c1b2-8d38-4939-bfd6-d379f27b3a86' User entered 'None (0)'	System	14 Aug 2020 21:44:47
	System	14 Aug 2020 21:44:47

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:38', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8ba7c1b2-8d38-4939-bfd6-d379f27b3a86' User entered 'None (0)'	System	14 Aug 2020 21:44:47
	System	14 Aug 2020 21:44:47

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:43', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8ba7c1b2-8d38-4939-bfd6-d379f27b3a86' User entered 'No (N)'	System	14 Aug 2020 21:44:47
	System	14 Aug 2020 21:44:47

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T14:44:45', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8ba7c1b2-8d38-4939-bfd6-d379f27b3a86' User entered '14 Aug 2020 14:44'	System	14 Aug 2020 21:44:47
	System	14 Aug 2020 21:44:47

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 14:32'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 17:02'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 21:24:36



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:14', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '42b8d98a-3c9f-4862-9da2-031bb266671c' User entered 'None (0)'	System	15 Aug 2020 02:52:33
	System	15 Aug 2020 02:52:33

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:16', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '42b8d98a-3c9f-4862-9da2-031bb266671c' User entered 'None (0)'	System	15 Aug 2020 02:52:33
	System	15 Aug 2020 02:52:33

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:17', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '42b8d98a-3c9f-4862-9da2-031bb266671c' User entered 'None (0)'	System	15 Aug 2020 02:52:33
	System	15 Aug 2020 02:52:33

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:18', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '42b8d98a-3c9f-4862-9da2-031bb266671c' User entered 'None (0)'	System	15 Aug 2020 02:52:33
	System	15 Aug 2020 02:52:33

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:20', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '42b8d98a-3c9f-4862-9da2-031bb266671c' User entered 'None (0)'	System	15 Aug 2020 02:52:33
	System	15 Aug 2020 02:52:33

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:21', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '42b8d98a-3c9f-4862-9da2-031bb266671c' User entered 'None (0)'	System	15 Aug 2020 02:52:33
	System	15 Aug 2020 02:52:33

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:28', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '42b8d98a-3c9f-4862-9da2-031bb266671c' User entered 'No (N)'	System	15 Aug 2020 02:52:33
	System	15 Aug 2020 02:52:33

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-14T19:52:29', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '42b8d98a-3c9f-4862-9da2-031bb266671c' User entered '14 Aug 2020 19:52'	System	15 Aug 2020 02:52:33
	System	15 Aug 2020 02:52:33



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '14 Aug 2020 17:57'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 2'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:35', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0a6b6de3-d43d-4327-bf3e-82682c03f631' User entered 'None (0)'	System	15 Aug 2020 19:08:54
	System	15 Aug 2020 19:08:54

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:38', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0a6b6de3-d43d-4327-bf3e-82682c03f631' User entered 'None (0)'	System	15 Aug 2020 19:08:54
	System	15 Aug 2020 19:08:54

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:40', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0a6b6de3-d43d-4327-bf3e-82682c03f631' User entered 'None (0)'	System	15 Aug 2020 19:08:54
	System	15 Aug 2020 19:08:54

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:42', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0a6b6de3-d43d-4327-bf3e-82682c03f631' User entered 'None (0)'	System	15 Aug 2020 19:08:54
	System	15 Aug 2020 19:08:54

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:43', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0a6b6de3-d43d-4327-bf3e-82682c03f631' User entered 'None (0)'	System	15 Aug 2020 19:08:54
	System	15 Aug 2020 19:08:54



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:45', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0a6b6de3-d43d-4327-bf3e-82682c03f631' User entered 'None (0)'	System	15 Aug 2020 19:08:54
	System	15 Aug 2020 19:08:54

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:50', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0a6b6de3-d43d-4327-bf3e-82682c03f631' User entered 'No (N)'	System	15 Aug 2020 19:08:54
	System	15 Aug 2020 19:08:54

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-15T12:08:53', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0a6b6de3-d43d-4327-bf3e-82682c03f631' User entered '15 Aug 2020 12:08'	System	15 Aug 2020 19:08:54
	System	15 Aug 2020 19:08:54

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 3'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:03', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1c3c7add-583e-4f96-8c6a-234fd9b4c0e5' User entered 'None (0)'	System	16 Aug 2020 19:04:16
	System	16 Aug 2020 19:04:16

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:04', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1c3c7add-583e-4f96-8c6a-234fd9b4c0e5' User entered 'None (0)'	System	16 Aug 2020 19:04:16
	System	16 Aug 2020 19:04:16



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:05', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1c3c7add-583e-4f96-8c6a-234fd9b4c0e5' User entered 'None (0)'	System	16 Aug 2020 19:04:16
	System	16 Aug 2020 19:04:16

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:06', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1c3c7add-583e-4f96-8c6a-234fd9b4c0e5' User entered 'None (0)'	System	16 Aug 2020 19:04:16
	System	16 Aug 2020 19:04:16

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:07', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1c3c7add-583e-4f96-8c6a-234fd9b4c0e5' User entered 'None (0)'	System	16 Aug 2020 19:04:16
	System	16 Aug 2020 19:04:16

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:09', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1c3c7add-583e-4f96-8c6a-234fd9b4c0e5' User entered 'None (0)'	System	16 Aug 2020 19:04:16
	System	16 Aug 2020 19:04:16

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:11', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1c3c7add-583e-4f96-8c6a-234fd9b4c0e5'	System	16 Aug 2020 19:04:16
User entered 'No (N)'	System	16 Aug 2020 19:04:16

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-16T12:04:12', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1c3c7add-583e-4f96-8c6a-234fd9b4c0e5'	System	16 Aug 2020 19:04:16
User entered '16 Aug 2020 12:04'	System	16 Aug 2020 19:04:16

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 21:24:36



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 4'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:43', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dc3060ab-079b-41b9-a0a0-308df21b1863' User entered 'None (0)'	System	17 Aug 2020 19:03:58
	System	17 Aug 2020 19:03:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:45', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dc3060ab-079b-41b9-a0a0-308df21b1863' User entered 'None (0)'	System	17 Aug 2020 19:03:58
	System	17 Aug 2020 19:03:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:46', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dc3060ab-079b-41b9-a0a0-308df21b1863' User entered 'None (0)'	System	17 Aug 2020 19:03:58
	System	17 Aug 2020 19:03:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:47', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dc3060ab-079b-41b9-a0a0-308df21b1863' User entered 'None (0)'	System	17 Aug 2020 19:03:58
	System	17 Aug 2020 19:03:58

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:04**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:48', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dc3060ab-079b-41b9-a0a0-308df21b1863' User entered 'None (0)'	System	17 Aug 2020 19:03:58
	System	17 Aug 2020 19:03:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:49', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dc3060ab-079b-41b9-a0a0-308df21b1863' User entered 'None (0)'	System	17 Aug 2020 19:03:58
	System	17 Aug 2020 19:03:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:51', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dc3060ab-079b-41b9-a0a0-308df21b1863' User entered 'No (N)'	System	17 Aug 2020 19:03:58
	System	17 Aug 2020 19:03:58



**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-17T12:03:53', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dc3060ab-079b-41b9-a0a0-308df21b1863' User entered '17 Aug 2020 12:03'	System	17 Aug 2020 19:03:58
	System	17 Aug 2020 19:03:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 5'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:15', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6f860426-070f-4209-be6e-fdd6ee2d1017'	System	18 Aug 2020 19:01:29
User entered 'None (0)'	System	18 Aug 2020 19:01:29

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:17', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6f860426-070f-4209-be6e-fdd6ee2d1017' User entered 'None (0)'	System	18 Aug 2020 19:01:29
	System	18 Aug 2020 19:01:29

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:18', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6f860426-070f-4209-be6e-fdd6ee2d1017' User entered 'None (0)'	System	18 Aug 2020 19:01:29
	System	18 Aug 2020 19:01:29

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:20', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6f860426-070f-4209-be6e-fdd6ee2d1017' User entered 'None (0)'	System	18 Aug 2020 19:01:29
	System	18 Aug 2020 19:01:29



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:21', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6f860426-070f-4209-be6e-fdd6ee2d1017' User entered 'None (0)'	System	18 Aug 2020 19:01:29
	System	18 Aug 2020 19:01:29

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:23', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6f860426-070f-4209-be6e-fdd6ee2d1017'	System	18 Aug 2020 19:01:29
User entered 'None (0)'	System	18 Aug 2020 19:01:29

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:25', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6f860426-070f-4209-be6e-fdd6ee2d1017'	System	18 Aug 2020 19:01:29
User entered 'No (N)'	System	18 Aug 2020 19:01:29

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-18T12:01:28', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6f860426-070f-4209-be6e-fdd6ee2d1017' User entered '18 Aug 2020 12:01'	System	18 Aug 2020 19:01:29
	System	18 Aug 2020 19:01:29

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 6'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:46', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6e6038a5-374a-4be3-a164-8e77165ee7fa' User entered 'None (0)'	System	19 Aug 2020 19:13:58
	System	19 Aug 2020 19:13:58



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:47', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6e6038a5-374a-4be3-a164-8e77165ee7fa' User entered 'None (0)'	System	19 Aug 2020 19:13:58
	System	19 Aug 2020 19:13:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:48', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6e6038a5-374a-4be3-a164-8e77165ee7fa' User entered 'None (0)'	System	19 Aug 2020 19:13:58
	System	19 Aug 2020 19:13:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:49', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6e6038a5-374a-4be3-a164-8e77165ee7fa' User entered 'None (0)'	System	19 Aug 2020 19:13:58
	System	19 Aug 2020 19:13:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:50', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6e6038a5-374a-4be3-a164-8e77165ee7fa' User entered 'None (0)'	System	19 Aug 2020 19:13:58
	System	19 Aug 2020 19:13:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:51', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6e6038a5-374a-4be3-a164-8e77165ee7fa' User entered 'None (0)'	System	19 Aug 2020 19:13:58
	System	19 Aug 2020 19:13:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:54', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6e6038a5-374a-4be3-a164-8e77165ee7fa' User entered 'No (N)'	System	19 Aug 2020 19:13:58
	System	19 Aug 2020 19:13:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-19T12:13:56', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6e6038a5-374a-4be3-a164-8e77165ee7fa' User entered '19 Aug 2020 12:13'	System	19 Aug 2020 19:13:58
	System	19 Aug 2020 19:13:58

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 21:24:36



**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 7'	System	14 Aug 2020 21:24:36

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAF890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:34', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fd7488a6-9c2e-45b2-b2b2-6056fb4f8858' User entered 'None (0)'	System	20 Aug 2020 19:00:50
	System	20 Aug 2020 19:00:50

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:04**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAF890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:35', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fd7488a6-9c2e-45b2-b2b2-6056fb4f8858' User entered 'None (0)'	System	20 Aug 2020 19:00:50
	System	20 Aug 2020 19:00:50

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:36', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fd7488a6-9c2e-45b2-b2b2-6056fb4f8858' User entered 'None (0)'	System	20 Aug 2020 19:00:50
	System	20 Aug 2020 19:00:50

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAF890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:37', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fd7488a6-9c2e-45b2-b2b2-6056fb4f8858' User entered 'None (0)'	System	20 Aug 2020 19:00:50
	System	20 Aug 2020 19:00:50

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:04**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:38', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fd7488a6-9c2e-45b2-b2b2-6056fb4f8858' User entered 'None (0)'	System	20 Aug 2020 19:00:50
	System	20 Aug 2020 19:00:50

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:39', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fd7488a6-9c2e-45b2-b2b2-6056fb4f8858' User entered 'None (0)'	System	20 Aug 2020 19:00:50
	System	20 Aug 2020 19:00:50



US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:45', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fd7488a6-9c2e-45b2-b2b2-6056fb4f8858'	System	20 Aug 2020 19:00:50
User entered 'No (N)'	System	20 Aug 2020 19:00:50

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-08-20T12:00:47', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'fd7488a6-9c2e-45b2-b2b2-6056fb4f8858'	System	20 Aug 2020 19:00:50
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 19:00:50

US3112266

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 21:24:36

**US3112266**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 21:01:31

US3112266

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 21:01:31

US3112266

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 21:01:31

US3112266

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 21:01:31



US3112266

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 21:01:34

US3112266

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'I'	System	21 Aug 2020 21:01:34

US3112266

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 00:17:19

US3112266

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 00:17:19

US3112266

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 00:17:19

US3112266

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 00:17:19

US3112266

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 00:17:26

US3112266

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered '1'	System	29 Aug 2020 00:17:26



US3112266

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:19:52

US3112266

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:19:52

US3112266

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:19:52

US3112266

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:19:52

US3112266

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:19:57

US3112266

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'I'	System	04 Sep 2020 17:19:57

US3112266

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Matthew Musikanth	26 Oct 2020 20:26:37
User entered 'Yes (Y)'	(b) (4)	
	Natalie Moy (b) (4)	08 Oct 2020 23:14:03
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty; reason for change Data Entry Error	(b) (4)	
	Matthew Musikanth	26 Oct 2020 20:26:37
	(b) (4)	
User entered '15 Sep 2020'	Natalie Moy (b) (4)	08 Oct 2020 23:14:03
	(b) (4)	



US3112266

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty; reason for change Data Entry Error	(b) (4)	26 Oct 2020 20:26:37
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	08 Oct 2020 23:14:03
	Natalie Moy (b) (4)	
	(b) (4)	

**US3112266**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:04**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'VISIT2'	System	08 Oct 2020 23:14:03

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	



US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42



US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	



US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42



US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:42
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:42

US3112266

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:47
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:47
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:53
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) Matthew Musikanth (b) (4)	26 Oct 2020 20:26:53

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 20:26:53

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:53



US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:53
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:53
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:53

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:53
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:53

US3112266

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:53

US3112266

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:57
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:57
	(b) (4)	



US3112266

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:26:57
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:26:57

US3112266

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:52:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:27:02
	(b) (4)	

**US3112266**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:27:02

US3112266

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	26 Oct 2020 20:27:02
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:27:02
	(b) (4)	

**US3112266**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:27:02

US3112266

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:27:02



US3112266

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	26 Oct 2020 20:27:02
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	26 Oct 2020 20:27:02
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered empty.	System	26 Oct 2020 20:27:02

US3112266

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	26 Oct 2020 20:27:06
	(b) (4)	

US3112266

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered '1'	System	26 Oct 2020 20:27:06

US3112266

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'No (N)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:16
	(b) (4)	

US3112266

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:16
	(b) (4)	

US3112266

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:16
	(b) (4)	



US3112266

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Patient in Convalescent Phase'	Matthew Musikanth (b) (4)	11 Dec 2020 00:32:16

US3112266

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:48:27
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:20
	(b) (4)	

US3112266

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'I'	System	11 Dec 2020 00:32:20

**US3112266**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:04**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:26
	(b) (4)	

US3112266

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:26
	(b) (4)	

US3112266

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:26
	(b) (4)	

US3112266

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Patient in Convalescent Phase'	Matthew Musikanth (b) (4)	11 Dec 2020 00:32:26

US3112266

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:30
	(b) (4)	



US3112266

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'I'	System	11 Dec 2020 00:32:30

US3112266

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:37
	(b) (4)	

US3112266

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:37
	(b) (4)	

US3112266

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:37
	(b) (4)	

US3112266

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Patient in Convalescent Phase'	Matthew Musikanth (b) (4)	11 Dec 2020 00:32:37

US3112266

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:41
	(b) (4)	

**US3112266**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:04**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'I'	System	11 Dec 2020 00:32:41

US3112266

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'No (N)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:50
	(b) (4)	



US3112266

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:50
	(b) (4)	

US3112266

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:50
	(b) (4)	

US3112266

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'VISIT3'	System	11 Dec 2020 00:32:50

US3112266

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:13:22
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:32:54
	(b) (4)	

US3112266

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered '1'	System	11 Dec 2020 00:32:54

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 64'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

[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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-18T18:14:36', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6115d94d-2eef-4ccd-ae51-2c18a4cfe46c' User entered 'No (N)'	System	19 Oct 2020 01:15:03
	System	19 Oct 2020 01:15:03

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

Have you been exposed to someone with 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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-18T18:14:43', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6115d94d-2eef-4ccd-ae51-2c18a4cfe46c'	System	19 Oct 2020 01:15:03
User entered 'Yes (Y)'	System	19 Oct 2020 01:15:03



**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-18T18:14:50', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6115d94d-2eef-4ccd-ae51-2c18a4cfe46c'	System	19 Oct 2020 01:15:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Oct 2020 01:15:03

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-18T18:14:53', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '6115d94d-2eef-4ccd-ae51-2c18a4cfe46c' User entered '18 Oct 2020 18:14:53'	System	19 Oct 2020 01:15:03
	System	19 Oct 2020 01:15:03

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 21:24:36

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 21:24:36

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 71'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

[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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-21T21:32:17', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7cf17ccf-1c0a-4585-a416-e039215cc2ac'	System	22 Oct 2020 04:32:29
User entered 'No (N)'	System	22 Oct 2020 04:32:29

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

Have you been exposed to someone with 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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-21T21:32:22', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7cf17ccf-1c0a-4585-a416-e039215cc2ac'	System	22 Oct 2020 04:32:29
User entered 'No (N)'	System	22 Oct 2020 04:32:29

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-21T21:32:26', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7cf17ccf-1c0a-4585-a416-e039215cc2ac'	System	22 Oct 2020 04:32:29
User entered '21 Oct 2020 21:32:26'	System	22 Oct 2020 04:32:29



**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 21:24:36

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 78'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

[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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-28T12:29:40', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '926d9e70-be5e-4ef3-a5f1-67bca1cc1281' User entered 'No (N)'	System	28 Oct 2020 19:29:50
	System	28 Oct 2020 19:29:50

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

Have you been exposed to someone with 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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-28T12:29:42', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '926d9e70-be5e-4ef3-a5f1-67bca1cc1281'	System	28 Oct 2020 19:29:50
User entered 'No (N)'	System	28 Oct 2020 19:29:50

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-10-28T12:29:45', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '926d9e70-be5e-4ef3-a5f1-67bca1cc1281' User entered '28 Oct 2020 12:29:45'	System	28 Oct 2020 19:29:50
	System	28 Oct 2020 19:29:50

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 21:24:36

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 21:24:36



US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 92'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

[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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-11T10:38:55', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f8e91bb7-774b-4426-bdd6-b5bcca6c31e0'	System	11 Nov 2020 18:39:05
User entered 'No (N)'	System	11 Nov 2020 18:39:05
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

Have you been exposed to someone with 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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-11T10:38:58', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f8e91bb7-774b-4426-bdd6-b5bcca6c31e0'	System	11 Nov 2020 18:39:05
User entered 'No (N)'	System	11 Nov 2020 18:39:05
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-11T10:39:01', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f8e91bb7-774b-4426-bdd6-b5bcca6c31e0'	System	11 Nov 2020 18:39:05
User entered '11 Nov 2020 10:39:01'	System	11 Nov 2020 18:39:05
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24
Data entry locked.	System	14 Aug 2020 21:24:36
User entered 'Day 99'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-18T09:15:11', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '128de5df-1d91-43b6-bf6f-69c0a4d93721'	System	18 Nov 2020 17:15:21
User entered 'No (N)'	System	18 Nov 2020 17:15:21
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24



US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

Have you been exposed to someone with 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)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-18T09:15:14', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '128de5df-1d91-43b6-bf6f-69c0a4d93721'	System	18 Nov 2020 17:15:21
User entered 'No (N)'	System	18 Nov 2020 17:15:21
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24

**US3112266**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-18T09:15:16', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '128de5df-1d91-43b6-bf6f-69c0a4d93721'	System	18 Nov 2020 17:15:21
User entered '18 Nov 2020 09:15:16'	System	18 Nov 2020 17:15:21
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 21:24:36

US3112266

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:27
DataPoint Activated.	System	30 Oct 2020 19:00:10
DataPoint Inactivated.	System	30 Oct 2020 18:57:24
Data entry locked.	System	14 Aug 2020 21:24:36
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 21:24:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-25T11:00:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '2e0448ee-2ff5-4d33-b44c-7aa789da02ab' User entered 'No (N)'	System	25 Nov 2020 19:00:09

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-25T11:00:02', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '2e0448ee-2ff5-4d33-b44c-7aa789da02ab'	System	25 Nov 2020 19:00:09
User entered 'No (N)'	System	25 Nov 2020 19:00:09

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-25T11:00:06', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '2e0448ee-2ff5-4d33-b44c-7aa789da02ab' User entered '25 Nov 2020 11:00:06'	System	25 Nov 2020 19:00:09
	System	25 Nov 2020 19:00:09



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-29T15:45:20', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'd5d3363f-50f9-415d-b5fa-e5387eed046d'	System	29 Nov 2020 23:45:26
User entered 'No (N)'	System	29 Nov 2020 23:45:26

US3112266

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:04

Have you been exposed to someone with 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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-29T15:45:21', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'd5d3363f-50f9-415d-b5fa-e5387eed046d'	System	29 Nov 2020 23:45:26
User entered 'No (N)'	System	29 Nov 2020 23:45:26

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-11-29T15:45:23', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'd5d3363f-50f9-415d-b5fa-e5387eed046d' User entered '29 Nov 2020 15:45:23'	System	29 Nov 2020 23:45:26
	System	29 Nov 2020 23:45:26

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-07T09:04:49', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1b553caa-10ad-4cce-9029-684d0b918caa' User entered 'No (N)'	System	07 Dec 2020 17:04:59

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-07T09:04:51', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1b553caa-10ad-4cce-9029-684d0b918caa' User entered 'No (N)'	System	07 Dec 2020 17:04:59

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-07T09:04:54', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1b553caa-10ad-4cce-9029-684d0b918caa' User entered '07 Dec 2020 09:04:54'	System	07 Dec 2020 17:04:59
	System	07 Dec 2020 17:04:59

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-13T00:01:26', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8732dec1-03e2-4008-b070-f0019fac91ac' User entered 'No (N)'	System	13 Dec 2020 08:01:37
	System	13 Dec 2020 08:01:37



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-13T00:01:29', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8732dec1-03e2-4008-b070-f0019fac91ac'	System	13 Dec 2020 08:01:37
User entered 'No (N)'	System	13 Dec 2020 08:01:37

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-13T00:01:30', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8732dec1-03e2-4008-b070-f0019fac91ac' User entered '13 Dec 2020 00:01:30'	System	13 Dec 2020 08:01:37
	System	13 Dec 2020 08:01:37

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-20T00:03:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1a8bda67-f7ee-45ec-8641-cd3ed59f47bc'	System	20 Dec 2020 08:03:16
User entered 'No (N)'	System	20 Dec 2020 08:03:16

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-20T00:03:08', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1a8bda67-f7ee-45ec-8641-cd3ed59f47bc'	System	20 Dec 2020 08:03:16
User entered 'No (N)'	System	20 Dec 2020 08:03:16

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-20T00:03:12', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '1a8bda67-f7ee-45ec-8641-cd3ed59f47bc' User entered '20 Dec 2020 00:03:12'	System	20 Dec 2020 08:03:16
	System	20 Dec 2020 08:03:16



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-27T00:01:18', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7398ee28-6fa1-4fd6-8b03-3e7cf990f5cc' User entered 'No (N)'	System	27 Dec 2020 08:01:27
	System	27 Dec 2020 08:01:27

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-27T00:01:21', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7398ee28-6fa1-4fd6-8b03-3e7cf990f5cc' User entered 'No (N)'	System	27 Dec 2020 08:01:27
	System	27 Dec 2020 08:01:27

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2020-12-27T00:01:23', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7398ee28-6fa1-4fd6-8b03-3e7cf990f5cc' User entered '27 Dec 2020 00:01:23'	System	27 Dec 2020 08:01:27
	System	27 Dec 2020 08:01:27

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-03T00:05:47', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '40fa7736-c392-4c37-96c2-a7c77be5f084' User entered 'No (N)'	System	03 Jan 2021 08:05:56
	System	03 Jan 2021 08:05:56

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-03T00:05:49', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '40fa7736-c392-4c37-96c2-a7c77be5f084'	System	03 Jan 2021 08:05:56
User entered 'No (N)'	System	03 Jan 2021 08:05:56

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-03T00:05:52', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '40fa7736-c392-4c37-96c2-a7c77be5f084' User entered '03 Jan 2021 00:05:52'	System	03 Jan 2021 08:05:56
	System	03 Jan 2021 08:05:56

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-11T14:33:06', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'b4fb1c76-c98e-4613-98c9-9f5df79393aa'	System	11 Jan 2021 22:33:21
User entered 'No (N)'	System	11 Jan 2021 22:33:21



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-11T14:33:08', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'b4fb1c76-c98e-4613-98c9-9f5df79393aa'	System	11 Jan 2021 22:33:21
User entered 'No (N)'	System	11 Jan 2021 22:33:21

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-11T14:33:16', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'b4fb1c76-c98e-4613-98c9-9f5df79393aa' User entered '11 Jan 2021 14:33:16'	System	11 Jan 2021 22:33:21

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-17T00:01:20', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'e8438d2a-9c26-4de2-8d89-ca5d106b1097'	System	17 Jan 2021 08:01:29
User entered 'No (N)'	System	17 Jan 2021 08:01:29

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-17T00:01:23', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'e8438d2a-9c26-4de2-8d89-ca5d106b1097'	System	17 Jan 2021 08:01:29
User entered 'No (N)'	System	17 Jan 2021 08:01:29

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-17T00:01:25', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'e8438d2a-9c26-4de2-8d89-ca5d106b1097'	System	17 Jan 2021 08:01:29
User entered '17 Jan 2021 00:01:25'	System	17 Jan 2021 08:01:29



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-24T00:11:52', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0bd0ca7e-1bc8-44c7-9b6b-b8e86eecf07e' User entered 'No (N)'	System	24 Jan 2021 08:12:04
	System	24 Jan 2021 08:12:04

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-24T00:11:57', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0bd0ca7e-1bc8-44c7-9b6b-b8e86eecf07e' User entered 'No (N)'	System	24 Jan 2021 08:12:04

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-24T00:12:01', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0bd0ca7e-1bc8-44c7-9b6b-b8e86eecf07e' User entered '24 Jan 2021 00:12:01'	System	24 Jan 2021 08:12:04
	System	24 Jan 2021 08:12:04

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-31T00:01:33', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'b6394a55-14d8-4186-8917-424e04e0a533'	System	31 Jan 2021 07:01:41
User entered 'No (N)'	System	31 Jan 2021 07:01:41

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-31T00:01:36', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'b6394a55-14d8-4186-8917-424e04e0a533'	System	31 Jan 2021 07:01:41
User entered 'No (N)'	System	31 Jan 2021 07:01:41

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-01-31T00:01:39', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'b6394a55-14d8-4186-8917-424e04e0a533'	System	31 Jan 2021 07:01:41
User entered '31 Jan 2021 00:01:39'	System	31 Jan 2021 07:01:41

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-02-07T14:06:14', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '602d5473-9e83-41bf-9e54-550a4815bc94' User entered 'No (N)'	System	07 Feb 2021 22:06:20
	System	07 Feb 2021 22:06:20



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (2ECA890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-02-07T14:06:16', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '602d5473-9e83-41bf-9e54-550a4815bc94' User entered 'No (N)'	System	07 Feb 2021 22:06:20
	System	07 Feb 2021 22:06:20

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ECAf890-55F7-43AD-B8B0-6947C96A5D6D)', Time: '2021-02-07T14:06:18', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '602d5473-9e83-41bf-9e54-550a4815bc94' User entered '07 Feb 2021 14:06:18'	System	07 Feb 2021 22:06:20
	System	07 Feb 2021 22:06:20

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-14T00:42:43', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f488f919-ba1f-4dbe-bfa7-6a43bf240085' User entered 'No (N)'	System	14 Feb 2021 08:42:49

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-14T00:42:46', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f488f919-ba1f-4dbe-bfa7-6a43bf240085' User entered 'No (N)'	System	14 Feb 2021 08:42:49

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-14T00:42:47', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f488f919-ba1f-4dbe-bfa7-6a43bf240085' User entered '14 Feb 2021 00:42:47'	System	14 Feb 2021 08:42:49
	System	14 Feb 2021 08:42:49



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-21T00:12:34', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f7ab48b8-28ef-43c3-abd2-32099164ac3d' User entered 'No (N)'	System	21 Feb 2021 08:12:44
	System	21 Feb 2021 08:12:44

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-21T00:12:36', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f7ab48b8-28ef-43c3-abd2-32099164ac3d' User entered 'No (N)'	System	21 Feb 2021 08:12:44
	System	21 Feb 2021 08:12:44

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-21T00:12:38', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'f7ab48b8-28ef-43c3-abd2-32099164ac3d' User entered '21 Feb 2021 00:12:38'	System	21 Feb 2021 08:12:44
	System	21 Feb 2021 08:12:44

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-28T00:01:36-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '2539ed84-63aa-4736-b214-85c318fd3a3d' User entered 'No (N)'	System	28 Feb 2021 08:01:45
	System	28 Feb 2021 08:01:45

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-28T00:01:38-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '2539ed84-63aa-4736-b214-85c318fd3a3d' User entered 'No (N)'	System	28 Feb 2021 08:01:45
	System	28 Feb 2021 08:01:45

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-28T00:01:40-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '2539ed84-63aa-4736-b214-85c318fd3a3d' User entered '28 Feb 2021 08:01:40'	System	28 Feb 2021 08:01:45
	System	28 Feb 2021 08:01:45

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-10T09:09:26-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'c6f610bf-dc93-448f-a509-ed76b751781f'	System	10 Mar 2021 17:18:45
User entered 'No (N)'	System	10 Mar 2021 17:18:45



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-10T09:09:28-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'c6f610bf-dc93-448f-a509-ed76b751781f'	System	10 Mar 2021 17:18:45
User entered 'No (N)'	System	10 Mar 2021 17:18:45

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-10T09:09:30-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'c6f610bf-dc93-448f-a509-ed76b751781f' User entered '10 Mar 2021 09:09:30'	System	10 Mar 2021 17:18:45
	System	10 Mar 2021 17:18:45

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-14T00:02:17-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dccee628-501e-4601-b510-50b5cbbd3e0f' User entered 'No (N)'	System	14 Mar 2021 08:02:24
	System	14 Mar 2021 08:02:24

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-14T00:02:19-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dccee628-501e-4601-b510-50b5cbbd3e0f' User entered 'No (N)'	System	14 Mar 2021 08:02:24
	System	14 Mar 2021 08:02:24

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-14T00:02:21-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: 'dccee628-501e-4601-b510-50b5cbbd3e0f' User entered '14 Mar 2021 00:02:21'	System	14 Mar 2021 08:02:24
	System	14 Mar 2021 08:02:24



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-24T15:20:17-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0d8139c0-1685-44b6-881f-12ffdd441a67'	System	24 Mar 2021 22:20:28
User entered 'No (N)'	System	24 Mar 2021 22:20:28

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-24T15:20:21-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0d8139c0-1685-44b6-881f-12ffdd441a67'	System	24 Mar 2021 22:20:28
User entered 'No (N)'	System	24 Mar 2021 22:20:28

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-24T15:20:23-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '0d8139c0-1685-44b6-881f-12ffdd441a67'	System	24 Mar 2021 22:20:28
User entered '24 Mar 2021 15:20:23'	System	24 Mar 2021 22:20:28

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-28T09:44:21-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '211c3c65-b41d-4df1-a38d-7896fa7964e0' User entered 'No (N)'	System	06 Apr 2021 19:00:21
	System	06 Apr 2021 19:00:21

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-28T09:44:23-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '211c3c65-b41d-4df1-a38d-7896fa7964e0'	System	06 Apr 2021 19:00:21
User entered 'No (N)'	System	06 Apr 2021 19:00:21

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-03-28T09:44:25-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '211c3c65-b41d-4df1-a38d-7896fa7964e0'	System	06 Apr 2021 19:00:21
User entered '28 Mar 2021 09:44:25'	System	06 Apr 2021 19:00:21

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-06T12:00:16-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '616a8a28-2815-42b5-bbf4-62fdfdbd63a0'	System	06 Apr 2021 19:00:24
User entered 'No (N)'	System	06 Apr 2021 19:00:24



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-06T12:00:18-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '616a8a28-2815-42b5-bbf4-62fdfdbd63a0'	System	06 Apr 2021 19:00:24
User entered 'No (N)'	System	06 Apr 2021 19:00:24

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-06T12:00:20-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '616a8a28-2815-42b5-bbf4-62fdfdbd63a0'	System	06 Apr 2021 19:00:24
User entered '06 Apr 2021 12:00:20'	System	06 Apr 2021 19:00:24

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-12T09:53:34-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '16c37209-672c-4e06-bde0-313ea2fdbba3b'	System	12 Apr 2021 16:53:50
User entered 'No (N)'	System	12 Apr 2021 16:53:50

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-12T09:53:36-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '16c37209-672c-4e06-bde0-313ea2fdbba3b' User entered 'No (N)'	System	12 Apr 2021 16:53:50
	System	12 Apr 2021 16:53:50

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-12T09:53:38-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '16c37209-672c-4e06-bde0-313ea2fdb3b'	System	12 Apr 2021 16:53:50
User entered '12 Apr 2021 09:53:38'	System	12 Apr 2021 16:53:50



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-18T00:02:35-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '281a7d21-c7f6-4960-ab6f-f351689a9244'	System	18 Apr 2021 07:02:42
User entered 'No (N)'	System	18 Apr 2021 07:02:42

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-18T00:02:37-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '281a7d21-c7f6-4960-ab6f-f351689a9244'	System	18 Apr 2021 07:02:42
User entered 'No (N)'	System	18 Apr 2021 07:02:42

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-18T00:02:39-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '281a7d21-c7f6-4960-ab6f-f351689a9244'	System	18 Apr 2021 07:02:42
User entered '18 Apr 2021 00:02:39'	System	18 Apr 2021 07:02:42

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-25T00:08:26-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7ac77da3-cc06-4cde-a8db-c1b5262986ef' User entered 'No (N)'	System	25 Apr 2021 07:08:35
	System	25 Apr 2021 07:08:35

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-25T00:08:28-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7ac77da3-cc06-4cde-a8db-c1b5262986ef' User entered 'No (N)'	System	25 Apr 2021 07:08:35

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-04-25T00:08:30-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '7ac77da3-cc06-4cde-a8db-c1b5262986ef' User entered '25 Apr 2021 00:08:30'	System	25 Apr 2021 07:08:35
	System	25 Apr 2021 07:08:35

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-05-02T00:16:01-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4bda0fb2-07df-4486-97d1-03117c380ca4'	System	02 May 2021 07:16:10
User entered 'No (N)'	System	02 May 2021 07:16:10



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Have you been exposed to someone with 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 (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-05-02T00:16:03-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4bda0fb2-07df-4486-97d1-03117c380ca4'	System	02 May 2021 07:16:10
User entered 'No (N)'	System	02 May 2021 07:16:10

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-05-02T00:16:05-07:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '4bda0fb2-07df-4486-97d1-03117c380ca4'	System	02 May 2021 07:16:10
User entered '02 May 2021 00:16:05'	System	02 May 2021 07:16:10

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:01:36



**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 08:01:36

**US3112266**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:01:36
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 08:01:36



US3112266

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:52:04**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-28T00:01:29-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8e07f81d-0d7f-47f7-a6b7-d933ffe807ab'	System	28 Feb 2021 08:01:37
User entered 'No (N)'	System	28 Feb 2021 08:01:37

US3112266

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:52:04

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27FA6FA1-0069-4921-BC0A-C68D383F4596)', Time: '2021-02-28T00:01:32-08:00', User OID: 'PatientReportedOutcome (US3112266)', ODM File OID: '8e07f81d-0d7f-47f7-a6b7-d933ffe807ab' User entered '28 Feb 2021 08:01:32'	System	28 Feb 2021 08:01:37
	System	28 Feb 2021 08:01:37

**US3112266**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:04**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:51
User entered 'No (N)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:33:18
	(b) (4)	

US3112266

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:51
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:33:18
	(b) (4)	

US3112266

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:51
User entered empty.	(b) (4) Matthew Musikanth	11 Dec 2020 00:33:18
	(b) (4)	

US3112266

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:51
User entered 'Contact inadvertently missed.'	Matthew Musikanth (b) (4)	11 Dec 2020 00:33:18

US3112266

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:51
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	11 Dec 2020 00:33:22
	(b) (4)	

US3112266

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:57:02
User entered 'I'	System	11 Dec 2020 00:33:22



**US3112266**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:04**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Dec 2020 00:33:37

US3112266

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '10 Dec 2020'	Matthew Musikanth (b) (4)	11 Dec 2020 00:33:37

**US3112266**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:04**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	11 Dec 2020 00:33:37

US3112266

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Matthew Musikanth (b) (4)	11 Dec 2020 00:33:37

US3112266

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Dec 2020 00:33:40

**US3112266**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:04**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered '1'	System	11 Dec 2020 00:33:40

US3112266

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 00:37:56

US3112266

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '11 Jan 2021'	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 00:37:56



US3112266

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 00:37:56

US3112266

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 00:37:56

US3112266

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 00:38:03

US3112266

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered 'I'	System	12 Jan 2021 00:38:03

US3112266

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Feb 2021 23:13:28

US3112266

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '8 Feb 2021'	Karen Mylerberg (b) (4) (b) (4)	22 Feb 2021 23:13:28

US3112266

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	22 Feb 2021 23:13:28

US3112266

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Feb 2021 23:13:28



US3112266

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Feb 2021 23:13:33

US3112266

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered 'I'	System	22 Feb 2021 23:13:33

US3112266

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 19Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 03:56:45
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 19Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 23:07:32
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 19Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 05:24:08
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:04

US3112266

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:04

US3112266

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:04

US3112266

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered 'VISIT4'	System	19 Mar 2021 21:30:04

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59



US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '08:39'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered '19 Mar 2021 08:39'	System	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '98.0' F	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '62'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered 'bpm'	System	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59



US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered 'breaths/min'	System	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '128'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered 'mmHg'	System	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '82'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered 'mmHg'	System	29 Mar 2021 14:33:59

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08

US3112266

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08

US3112266

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:11



US3112266

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:11

US3112266

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:19

US3112266

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:19

US3112266

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '09:05'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:19

US3112266

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered '19 Mar 2021 09:05'	System	19 Mar 2021 21:30:19

US3112266

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:22

US3112266

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:52:08
User entered 'I'	System	19 Mar 2021 21:30:22

US3112266

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 21:04:29



US3112266

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:27
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 21:04:29

US3112266

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Apr 2021 21:04:29

US3112266

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:27
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 21:04:29

US3112266

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 21:04:36

**US3112266**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:04**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 21:04:36

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:04

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:40
DataPoint Un-verified.	Matthew Musikanth	29 Oct 2020 21:22:59
	(b) (4)	
User entered '10 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth	29 Oct 2020 21:22:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:50:47
User entered '13 Sep 2020'	Matthew Musikanth	17 Sep 2020 20:10:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:04

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:42
Query 'Data is required. Please complete.' answered with 'confirmed unknown ' (Site from System).	Matthew Musikanth	29 Oct 2020 21:23:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 21:22:59
DataPoint Un-verified.	Matthew Musikanth	29 Oct 2020 21:22:59
	(b) (4)	
User entered empty; reason for change Data Entry Error	Matthew Musikanth	29 Oct 2020 21:22:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:50:47
User entered '10:17' reason for change: Data Entry Error	Matthew Musikanth	28 Oct 2020 23:50:17
	(b) (4)	
User entered '10:00'	Matthew Musikanth	17 Sep 2020 20:10:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:04

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:19
User entered empty.	System	29 Oct 2020 21:22:59
User entered '13 Sep 2020 10:17'	System	28 Oct 2020 23:50:17
User entered '13 Sep 2020 10:00'	System	17 Sep 2020 20:10:59



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:04

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:19
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:43
DataPoint Un-verified.	Matthew Musikanth	29 Oct 2020 21:22:59
	(b) (4)	
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Matthew Musikanth	29 Oct 2020 21:22:59
	(b) (4)	
User closed query 'Per ETRTR: Please complete data entry within an Illness Visit Folder, thanks.' (Site from CRA).	Joseph Settle (2934 - JSettle1)	29 Oct 2020 05:00:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:50:47
	(b) (4)	
Query 'Per ETRTR: Please complete data entry within an Illness Visit Folder, thanks.' answered with 'Updated' (Site from CRA).	Matthew Musikanth	07 Oct 2020 22:29:46
	(b) (4)	
User opened query 'Per ETRTR: Please complete data entry within an Illness Visit Folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Oct 2020 17:56:32
	(b) (4)	
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Matthew Musikanth	17 Sep 2020 20:10:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:04

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:50:47
User entered 'Yes (Y)'	Matthew Musikanth	17 Sep 2020 20:10:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 8 (Day 8)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 1 (Day 1)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:18
User closed query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:13:49
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
Query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' answered with 'updated as per paper file' (Site from DM).	Natalie Moy (b) (4)	27 Oct 2020 22:51:48
	(b) (4)	
User opened query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 21:49:26
User entered '13 Sep 2020'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:20
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:15
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '98'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	17 Sep 2020 20:23:59

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:17
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '97.9' F	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:27
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:32
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Mild (Mild)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:37
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:53
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:39:44
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:02
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:07
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:09
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:17
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:19
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:29
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:31
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:35
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:37
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:39
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:40:43
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	17 Sep 2020 20:23:59
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 10 (Day 10)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 3 (Day 3)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '15 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '97'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:41:54

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Mild (Mild)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Mild (Mild)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:42:34
User closed query 'Please clarify. Source indicates Yes for Headache. Please confirm and updated as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 23:42:31
Query 'Please clarify. Source indicates Yes for Headache. Please confirm and updated as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	29 Oct 2020 23:25:23
DataPoint Un-verified.	Matthew Musikanth (b) (4)	29 Oct 2020 23:25:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 23:25:18
User opened query 'Please clarify. Source indicates Yes for Headache. Please confirm and updated as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 23:18:13
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth (b) (4)	07 Oct 2020 21:41:54

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Matthew Musikanth	29 Oct 2020 22:16:08
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:17:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:41:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 11 (Day 11)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 4 (Day 4)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '16 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '96'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:43:36

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:43:36
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 12 (Day 12)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 5 (Day 5)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:28:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '17 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '98'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:44:26

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Mild (Mild)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:44:26
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 13 (Day 13)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 6 (Day 6)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '18 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '96'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:45:54

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Moderate (Moderate)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Severe (Severe)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Moderate (Moderate)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:45:54
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 14 (Day 14)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 7 (Day 7)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:30:59
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '19 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:46:25

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:46:25
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 15 (Day 15)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 8 (Day 8)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:31:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '20 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '97'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:47:02

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:14
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:31
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:02
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 16 (Day 16)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 9 (Day 9)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:32:02
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '21 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:32:10
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '98'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:47:38

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:32:07
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Oct 2020 21:48:29
User entered 'None (None)'	Matthew Musikanth (b) (4)	07 Oct 2020 21:47:38

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:47:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 17 (Day 17)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 10 (Day 10)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:32:32
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '22 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:32:38
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '96'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:48:29

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:32:43
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Mild (Mild)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:48:29
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 18 (Day 18)' reason for change:	Matthew Musikanth	29 Oct 2020 21:29:04
Data Entry Error	(b) (4)	
User entered 'Day 11 (Day 11)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:33:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '23 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:33:11
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '98'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:49:50

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:33:15
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Mild (Mild)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:49:50
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 20 (Day 20)' reason for change:	Matthew Musikanth	29 Oct 2020 21:30:29
Data Entry Error	(b) (4)	
User entered 'Day 13 (Day 13)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:36:24
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '25 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:36:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '98'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:50:34

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:36:30
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'Mild (Mild)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:25
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:50:34
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 21 (Day 21)' reason for change:	Matthew Musikanth	29 Oct 2020 21:30:29
Data Entry Error	(b) (4)	
User entered 'Day 14 (Day 14)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:37:00
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '26 Sep 2020'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:36:58
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '98'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:51:10

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:10
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 28 (Day 28)' reason for change:	Matthew Musikanth	29 Oct 2020 21:30:29
Data Entry Error	(b) (4)	
User entered 'Day 21 (Day 21)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:37:27
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '03 Oct 2020'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '0'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:37:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered '98'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	07 Oct 2020 21:51:58

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered missing code ND - Not Done.	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 23:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:53:16
User entered 'None (None)'	Matthew Musikanth	07 Oct 2020 21:51:58
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 1 (Day 1)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered '06 Sep 2020'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered '0'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	29 Oct 2020 21:24:56

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:12
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:24:56
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 2 (Day 2)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered '07 Sep 2020'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered '0'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	29 Oct 2020 21:25:43

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:15
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:25:43
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 3 (Day 3)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered '08 Sep 2020'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered '0'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	29 Oct 2020 21:26:11

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:18
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:11
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 4 (Day 4)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered '09 Sep 2020'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered '0'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	29 Oct 2020 21:26:38

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:31
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:26:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 5 (Day 5)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered '10 Sep 2020'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered '0'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	29 Oct 2020 21:27:13

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:24
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:13
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 6 (Day 6)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered '11 Sep 2020'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered '0'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	29 Oct 2020 21:27:41

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:27
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:27:41
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered 'Day 7 (Day 7)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered '12 Sep 2020'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered '0'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User entered '%'	System	29 Oct 2020 21:28:16

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered missing code ND - Not Done.	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'Mild (Mild)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:52:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:20:30
User entered 'None (None)'	Matthew Musikanth	29 Oct 2020 21:28:16
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
User entered '13 Sep 2020'	Matthew Musikanth	17 Sep 2020 20:24:12
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[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 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
User entered 'Yes (Y)'	Matthew Musikanth	17 Sep 2020 20:24:12
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

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 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
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)	13 Oct 2020 07:48:34
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 'Confirmed' (Site from System).	Matthew Musikanth (b) (4)	07 Oct 2020 22:18:13
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	07 Oct 2020 22:17:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Oct 2020 22:17:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 12:21:03
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Matthew Musikanth (b) (4)	17 Sep 2020 20:24:18
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 20:24:12
User entered empty.	Matthew Musikanth (b) (4)	17 Sep 2020 20:24:12

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
User entered '13 Sep 2020'	Matthew Musikanth	17 Sep 2020 20:24:12
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Matthew Musikanth	17 Sep 2020 20:24:12
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
User entered empty.	Matthew Musikanth	17 Sep 2020 20:24:12
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[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 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
User entered 'No (N)'	Matthew Musikanth	17 Sep 2020 20:24:12
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
User entered empty.	Matthew Musikanth	17 Sep 2020 20:24:12
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:01
User entered empty.	Matthew Musikanth	17 Sep 2020 20:24:12
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:52:04

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:03
User entered 'I'	System	07 Oct 2020 22:17:55

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

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 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

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 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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Generated On: 11 Aug 2021 21:52:04

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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Generated On: 11 Aug 2021 21:52:04

Evidence of Shock Requires  
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	



US3112266

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	



US3112266

Folder: Covid-19 Assessment 10 Sep 2020

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Generated On: 11 Aug 2021 21:52:04

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[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 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered 'No (N)'	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:52:04

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:39:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:25:50
User entered empty.	Matthew Musikanth	07 Oct 2020 22:18:38
	(b) (4)	

US3112266

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:52:04

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:26:00
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth	07 Oct 2020 22:29:57
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	17 Sep 2020 20:24:25
	(b) (4)	



**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:52:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered '15 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:52:04**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:52:04**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:52:04

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered '17 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:52:04**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:52:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01



US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:52:04

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered '19 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:52:04**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:52:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:52:04**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered '21 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:52:04**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:52:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:52:04

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered '26 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:52:04**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01



US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:52:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:52:04**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered '03 Oct 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

**US3112266**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:52:04**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:52:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:27
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 22:21:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 22:21:08
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:08
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 22:21:01
User entered empty.	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:52:04

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:39:44
User entered '10 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:27
User entered empty.	Matthew Musikanth (b) (4)	07 Oct 2020 22:21:01

US3112266

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:17:08
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:18:52

US3112266

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:17:08
User closed query 'Per CDM: Illness visit Day 1 is dated 07Aug2020. There is also an unscheduled visit dated 13Sep2020. Please clarify if these are the same visits. If yes, please agree to remove the data from the unscheduled visit or else clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:04:33
Query 'Per CDM: Illness visit Day 1 is dated 07Aug2020. There is also an unscheduled visit dated 13Sep2020. Please clarify if these are the same visits. If yes, please agree to remove the data from the unscheduled visit or else clarify.' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	26 Oct 2020 20:28:32
User opened query 'Per CDM: Illness visit Day 1 is dated 07Aug2020. There is also an unscheduled visit dated 13Sep2020. Please clarify if these are the same visits. If yes, please agree to remove the data from the unscheduled visit or else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 03:30:13
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:18:52

US3112266

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:17:08
User entered 'Home (Home)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:18:52



US3112266

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'SICKD1'	System	07 Oct 2020 22:18:52

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered '10:17'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered '13 Sep 2020 10:17'	System	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27
DataPoint set to visible.	System	07 Oct 2020 22:18:52

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27
DataPoint set to visible.	System	07 Oct 2020 22:18:52

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered '97.9' F	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27



US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered empty.	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered '72'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'bpm'	System	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered '16'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'breaths/min'	System	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered '130'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'mmHg'	System	07 Oct 2020 22:19:27



US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:27
User entered '84'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'mmHg'	System	07 Oct 2020 22:19:27

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07

US3112266

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07

US3112266

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:58
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:34

US3112266

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:18:58
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:34

US3112266

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:52:04

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:19:21
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:40

US3112266

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:52:04

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:19:21
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	07 Oct 2020 22:19:40



US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:29:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:33:12

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	30 Oct 2020 19:00:10
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	30 Oct 2020 18:57:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:29:07
User entered '10 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 20:33:12

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:29:07
User entered 'Home (Home)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:33:12

**US3112266**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:04**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'SICKD28'	System	26 Oct 2020 20:33:12

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Oct 2020 19:00:10
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Oct 2020 18:57:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered '10 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered '08:20'	Matthew Musikanth	26 Oct 2020 20:35:01
	(b) (4)	

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered '10 Oct 2020 08:20'	System	26 Oct 2020 20:35:01



US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01
DataPoint set to visible.	System	26 Oct 2020 20:33:12

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01
DataPoint set to visible.	System	26 Oct 2020 20:33:12

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered '98.2' F	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered '78'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'bpm'	System	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered '16'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01



US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'breaths/min'	System	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered '132'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'mmHg'	System	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:28
User entered '80'	Matthew Musikanth	26 Oct 2020 20:35:01
	(b) (4)	

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User entered 'mmHg'	System	26 Oct 2020 20:35:01

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:52:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07

US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:34
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:08



US3112266

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	30 Oct 2020 19:00:10
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	30 Oct 2020 18:57:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:34
User entered '10 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:08

US3112266

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:52:04

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:58
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:15

US3112266

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:52:04

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:16:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 23:30:58
User entered '10 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 20:35:15

US3112266

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

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:43:39

US3112266

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

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16 Feb 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:43:39

US3112266

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

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[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 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Home (Home)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:43:39

US3112266

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

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'UNBLND_DECIDE'	System	17 Feb 2021 00:43:39

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '6 Jan 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:44:12



US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:43:24

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User closed query 'Was the participant unblinded is No however, data is present. Please reconcile.' (Site from System).	System	17 Feb 2021 00:44:20
Query 'Was the participant unblinded is No however, data is present. Please reconcile.' answered by data change (Site from System).	System	17 Feb 2021 00:44:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:44:20
User opened query 'Was the participant unblinded is No however, data is present. Please reconcile.' (Site from System).	System	17 Feb 2021 00:44:12
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:44:12

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
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 12:43:24

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16 Feb 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:44:12

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:44:12

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:44:12

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:44:12

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:44:12



US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '1'	System	17 Feb 2021 00:44:12

US3112266

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

Form: Unblinding

Generated On: 11 Aug 2021 21:52:04

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'I'	System	17 Feb 2021 00:44:20
User entered empty.	System	17 Feb 2021 00:44:12

US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered empty.	System	17 Feb 2021 00:45:41
DataPoint set to visible.	System	17 Feb 2021 00:44:20

US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered empty.	System	17 Feb 2021 00:45:41
DataPoint set to visible.	System	17 Feb 2021 00:44:20



US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16 Feb 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '08:49'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '16 Feb 2021 08:49'	System	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '98.3' F	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41



US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '59'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'bpm'	System	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'breaths/min'	System	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '126'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mmHg'	System	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '77'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mmHg'	System	17 Feb 2021 00:45:41



US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:52:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered empty.	System	17 Feb 2021 00:45:41
DataPoint set to visible.	System	17 Feb 2021 00:44:20

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16 Feb 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '09:54'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '16 Feb 2021 09:54'	System	17 Feb 2021 00:45:41



US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '98.4' F	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '66'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'bpm'	System	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'breaths/min'	System	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '120'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41



US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mmHg'	System	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '74'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:41

US3112266

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mmHg'	System	17 Feb 2021 00:45:41

US3112266

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:59

US3112266

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16 Feb 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:45:59

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:46:44

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:46:44

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:46:44



US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mRNA-1273'	System	17 Feb 2021 00:46:44
DataPoint set to visible.	System	17 Feb 2021 00:44:20

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16 Feb 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:46:44

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '09:23'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:46:44

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '16 Feb 2021 09:23'	System	17 Feb 2021 00:46:44

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Left Arm (LEFT ARM)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:46:44

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'ONCE'	System	17 Feb 2021 00:46:44

US3112266

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

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 00:46:44

US3112266

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:47:19



US3112266

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16 Feb 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:47:19

US3112266

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '9:00'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:47:19

US3112266

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '16 Feb 2021 9:00'	System	17 Feb 2021 00:47:19

US3112266

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:47:29

US3112266

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16 Feb 2021'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:47:29

US3112266

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:52:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '08:53'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:47:29

**US3112266**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '16 Feb 2021 08:53'	System	17 Feb 2021 00:47:29

US3112266

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

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	17 Feb 2021 00:47:32



US3112266

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

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '1'	System	17 Feb 2021 00:47:32

**US3112266**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:04**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 18:57:57

US3112266

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered '23 Feb 2021'	Brenda Grande (b) (4)	23 Feb 2021 18:57:57
	(b) (4)	

**US3112266**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:04**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 18:57:57

US3112266

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 18:57:57

US3112266

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 18:58:04

**US3112266**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:04**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'I'	System	23 Feb 2021 18:58:04

**US3112266**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:04**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'I'	System	23 Feb 2021 18:58:04
DataPoint set to visible.	System	23 Feb 2021 18:58:04



US3112266

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:37

US3112266

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:37

US3112266

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:52:04

[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 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:30:37

**US3112266**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:04**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'OLD29'	System	19 Mar 2021 21:30:37

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '08:29'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25



US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '19 Mar 2021 08:29'	System	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '98.0' F	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '62'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'bpm'	System	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'breaths/min'	System	19 Mar 2021 21:31:25



US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '128'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

**US3112266**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mmHg'	System	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '82'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

**US3112266**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mmHg'	System	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '09:43'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25



**US3112266**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '19 Mar 2021 09:43'	System	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered '99.3' F	Brenda Grande (b) (4)	19 Mar 2021 21:31:25
	(b) (4)	

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

**US3112266**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:04**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '72'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

**US3112266**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:04**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'bpm'	System	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '16'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'breaths/min'	System	19 Mar 2021 21:31:25



US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '132'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

**US3112266**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:04**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mmHg'	System	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '86'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mmHg'	System	19 Mar 2021 21:31:25

US3112266

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:35

US3112266

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:52:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:35

US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:58

US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:58



US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:58

US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'mRNA-1273'	System	19 Mar 2021 21:31:58
DataPoint set to visible.	System	23 Feb 2021 18:58:04

US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:58

US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '09:12'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:58

**US3112266**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:52:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered '19 Mar 2021 09:12'	System	19 Mar 2021 21:31:58

US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Left Arm (LEFT ARM)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:31:58

US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'ONCE'	System	19 Mar 2021 21:31:58

US3112266

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'INTRAMUSCULAR'	System	19 Mar 2021 21:31:58



US3112266

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	19 Mar 2021 21:32:01

**US3112266**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:04**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'I'	System	19 Mar 2021 21:32:01

**US3112266**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:04**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:34:30

US3112266

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered '26 Mar 2021'	Brenda Grande (b) (4)	29 Mar 2021 14:34:30
	(b) (4)	

**US3112266**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:04**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:34:30

US3112266

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:34:30

US3112266

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 14:34:32

**US3112266**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:04**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:45:42
User entered 'I'	System	29 Mar 2021 14:34:32



**US3112266**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 21:52:04**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 22:33:42
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:41:23

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:32
User entered 'USA-US062-2020-mRNA-1273-P301000004'	System	01 Oct 2020 17:46:46
User entered 'New'	(b) (4), (b) (6)	01 Oct 2020 17:46:46

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
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)	01 Oct 2020 16:43:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:43:59
Data point term sent to Coder	System	01 Oct 2020 16:43:20
User entered 'Covid 19 Diagnosis'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
User closed query 'PV Query: Please consider updating start date to date of onset of symptoms, currently reported as 06 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:43:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:38:22
Query 'PV Query: Please consider updating start date to date of onset of symptoms, currently reported as 06 Sep 2020.' answered with 'updated' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 19:43:16
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 19:43:09
User entered '06 Sep 2020' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 19:43:09
User opened query 'PV Query: Please consider updating start date to date of onset of symptoms, currently reported as 06 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 16:37:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:27:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
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	01 Oct 2020 16:43:12
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 16:43:12
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	01 Oct 2020 16:42:45
User entered '10:55'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45



US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 16:43:12
User entered '13 Sep 2020 10:55'	System	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	26 Oct 2020 20:55:55
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:27:56
	(b) (4)	
User closed query 'PV Query: Please clarify event end date as subject has symptoms beyond current event date.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:42:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:38:59
Query 'PV Query: Please clarify event end date as subject has symptoms beyond current event date.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	09 Nov 2020 22:34:14
DataPoint Un-verified.	Matthew Musikanth (b) (4)	09 Nov 2020 22:34:07
User entered '26 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	09 Nov 2020 22:34:07
User opened query 'PV Query: Please clarify event end date as subject has symptoms beyond current event date.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 16:37:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:20:20
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	26 Oct 2020 20:56:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Oct 2020 20:56:14
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Oct 2020 20:56:14
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Oct 2020 20:55:55
User entered '16 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	26 Oct 2020 20:55:55

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:57:40
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

**US3112266**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:52:04**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45



US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45



US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:27:56
	(b) (4)	
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)	01 Nov 2020 12:22:30
User closed query 'Per CDM RQ: Dosing Discontinuation form is located in the End of Study folder.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 12:22:02
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 'Due to covid was selected.' (Site from System).	Matthew Musikanth (b) (4)	30 Oct 2020 19:03:59
Query 'Per CDM RQ: Dosing Discontinuation form is located in the End of Study folder.' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	30 Oct 2020 19:03:49
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	30 Oct 2020 18:59:29
User opened query 'Per CDM RQ: Dosing Discontinuation form is located in the End of Study folder.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:48:02
User closed query 'Per CDM RQ: Thank you for your response, however, the Dosing Discontinuation form has not been updated. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:48:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
Query 'Per CDM RQ: Thank you for your response, however, the Dosing Discontinuation form has not been updated. Please update accordingly.' answered with 'Please confirm if there is a dosing discount. form to be completed in EDC, and if so where it is populated as D29 visits have been completed as having not happened.' (Site from DM).	Matthew Musikanth (b) (4)	28 Oct 2020 18:25:19

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM RQ: Thank you for your response, however, the Dosing Discontinuation form has not been updated. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:01:46
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:01:46
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	26 Oct 2020 20:47:50
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 04:43:55
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered 'I'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45



US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:20:34
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	26 Oct 2020 20:56:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	26 Oct 2020 20:56:14
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:58:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:10:53
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:21:01
User closed query 'PV Query: Please provide the results of the COVID diagnostic test performed on 13 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:20:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:20:04
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'None' (Site from Safety).	Matthew Musikanth (b) (4)	26 Oct 2020 20:56:44
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	26 Oct 2020 20:49:44
Query 'PV Query: Please provide the results of the COVID diagnostic test performed on 13 Sep 2020.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	26 Oct 2020 20:49:26

US3112266

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:52:04

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:58:55
User opened query 'PV Query: Please provide the results of the COVID diagnostic test performed on 13 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:58:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:57:26
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 16:42:45

**US3112266**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 16:42:45

**US3112266**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 16:42:45

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:52:04

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:52:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:39:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth	26 Oct 2020 20:44:17
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:16:02



US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN MIGRAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 20:46:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 20:46:25
Data point term sent to Coder	System	26 Oct 2020 20:45:54
User entered 'Excedrin Migraine'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered 'Migraine/Headache'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered '250/65'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08



US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Oct 2020 19:00:10
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Oct 2020 18:57:24
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered '18 Sep 2020'	Matthew Musikanth	26 Oct 2020 20:45:08
	(b) (4)	

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered '0'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Oct 2020 19:00:10
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Oct 2020 18:57:24
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered '18 Sep 2020'	Matthew Musikanth	26 Oct 2020 20:45:08
	(b) (4)	

US3112266

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:40:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Oct 2020 20:45:08

US3112266

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 20:45:08



US3112266

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 20:45:08

US3112266

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 20:45:08

US3112266

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 21:52:04**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	23 Feb 2021 18:58:56

**US3112266**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 21:52:04**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	30 Oct 2020 18:59:29

US3112266

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:52:04

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered 'Due to SARS-COV-2 (COVID)'	Matthew Musikanth (b) (4)	30 Oct 2020 18:59:29

US3112266

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:52:04

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Matthew Musikanth (b) (4)	30 Oct 2020 18:59:29

US3112266

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:04

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Nov 2020 12:23:51
Query 'Data is required. Please complete.' answered with 'Dose discontinued, not study participation. eCRF inadvertently completed.' (Site from System).	Matthew Musikanth (b) (4)	30 Oct 2020 19:00:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:00:10
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	30 Oct 2020 19:00:10
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	30 Oct 2020 18:57:24

US3112266

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:04

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Nov 2020 12:23:53
Query 'Data is required. Please complete.' answered with 'Dose discontinued, not study participation. eCRF inadvertently completed.' (Site from System).	Matthew Musikanth (b) (4)	30 Oct 2020 19:00:55
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:00:10
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	30 Oct 2020 19:00:10
User entered 'AE (specify) (ADVERSE EVENT)'	Matthew Musikanth (b) (4)	30 Oct 2020 18:57:24



US3112266

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:04

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	30 Oct 2020 19:00:10
User entered 'Covid-19 Diagnosis'	Matthew Musikanth (b) (4)	30 Oct 2020 18:57:24

US3112266

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:04

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Matthew Musikanth (b) (4)	30 Oct 2020 18:57:24

US3112266

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:04

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Matthew Musikanth (b) (4)	30 Oct 2020 18:57:24

US3112266

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:04

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Matthew Musikanth (b) (4)	30 Oct 2020 18:57:24

US3112266

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:04

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
User entered empty.	Matthew Musikanth (b) (4)	30 Oct 2020 18:57:24

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'USA-US062-2020-MRNA-1273-P301000004'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46



US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'Laurie'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'Han-Conrad'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered '9040 Friars Rd St 540'	System	01 Oct 2020 17:46:46



US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'San Diego'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'CA'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered '92108'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:21:30
User entered 'US'	System	01 Oct 2020 17:49:52

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 15:46:47
User entered '2'	System	27 Oct 2020 17:21:43
User entered '1'	System	01 Oct 2020 17:49:52

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'USA-US062-2020-MRNA-1273-P301000004'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46



US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'Laurie'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'Han-Conrad'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered '9040 Friars Rd St 540'	System	01 Oct 2020 17:46:46



US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'San Diego'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'CA'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered '92108'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:21:30
User entered 'US'	System	01 Oct 2020 17:49:52

**US3112266**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:52:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 15:46:47
User entered '2'	System	27 Oct 2020 17:21:43
User entered '1'	System	01 Oct 2020 17:49:52

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:52:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
User entered '01/Oct/2020 13:49'	System	01 Oct 2020 17:49:52

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:52:04

**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.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:21:30
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 17:49:52

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'USA-US062-2020-MRNA-1273-P301000004'	System	01 Oct 2020 17:46:46



US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'Laurie'	System	01 Oct 2020 17:46:46



US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'Han-Conrad'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered '9040 Friars Rd St 540'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'San Diego'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'CA'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered '92108'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:21:30
User entered 'US'	System	01 Oct 2020 17:49:52

**US3112266**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:52:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 15:46:47
User entered '2'	System	27 Oct 2020 17:21:43
User entered '1'	System	01 Oct 2020 17:49:52

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:52:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
User entered '27/Oct/2020 13:21'	System	27 Oct 2020 17:21:43



US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:52:04

**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.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:46:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 17:21:43

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'USA-US062-2020-MRNA-1273-P301000004'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46



US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'No (N)'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'Laurie'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'Han-Conrad'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered '9040 Friars Rd St 540'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'San Diego'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered 'CA'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 17:49:46
User entered '92108'	System	01 Oct 2020 17:46:46

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:52:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:11:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:21:30
User entered 'US'	System	01 Oct 2020 17:49:52



**US3112266**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:52:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 15:46:47
User entered '2'	System	27 Oct 2020 17:21:43
User entered '1'	System	01 Oct 2020 17:49:52

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:52:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:47:15
User entered '10/Nov/2020 15:46'	System	10 Nov 2020 15:46:47

US3112266

Folder: SAE USA-US062-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:52:04

**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.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:47:15
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 15:46:47