

US3182145 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:32:13

All time stamps listed in this document are displayed in GMT

US3182145

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Participant ID

US3182145

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

US3182145

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:39:28

Generated On: 09 Jun 2021 15:32:13

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:39:28

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Date of Informed Consent (*dd MMM yyyy*) 4 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:39:29

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:39:29

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:39:29

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

Condition	TORN LEFT ROTATOR CUFF
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

Condition	LEFT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

Condition	OSTEOARTHRITIS-LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	09:06 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 09:06
Height (xxx.x)	167.6 cm
Weight (xxx.x)	87.0 kg
BMI (xxx.x)	30.97214 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:39:29

Generated On: 09 Jun 2021 15:32:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:39:29

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:39:29

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 100883

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

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)	04 AUG 2020
Time of assessment (00:00-23:59)	09:06 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 09:06
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

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)	04 AUG 2020
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 10:37
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	104 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

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) 4 AUG 2020

What was the treatment time? (00:00-23:59) 10:02 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 10:02

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 AUG 2020

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

04 AUG 2020 09:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	04 AUG 2020 09:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 10:34

PC Open Date & Time

04 AUG 2020 10:22

PC Close Date & Time

04 AUG 2020 12:52

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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	04 AUG 2020 19:32
PC Open Date & Time	04 AUG 2020 13:47
PC Close Date & Time	05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

98.8 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 AUG 2020 19:25

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 19:47

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

07 AUG 2020 17:04

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 18:16

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 17:50

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 21:20

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 10:36

PC Open Date & Time

04 AUG 2020 10:22

PC Close Date & Time

04 AUG 2020 12:52

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

04 AUG 2020 19:33

PC Open Date & Time

04 AUG 2020 13:47

PC Close Date & Time

05 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

05 AUG 2020 19:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

06 AUG 2020 19:48

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

07 AUG 2020 17:05

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

08 AUG 2020 18:16

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

09 AUG 2020 17:50

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

10 AUG 2020 21:20

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 10:36
PC Open Date & Time	04 AUG 2020 10:22
PC Close Date & Time	04 AUG 2020 12:52

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 19:34
PC Open Date & Time	04 AUG 2020 13:47
PC Close Date & Time	05 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

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 ☒

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 19:27
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2655

EAB) (1725)

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 19:49
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

52 of 2655

EAB) (1725)

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 17:05
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

54 of 2655

EAB) (1725)

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:17
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

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 ☒

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 17:50
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

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 ☒

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 22:38
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:13

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:13

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:16:43

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:16:43

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:16:44

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:16:44

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

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)	01 SEP 2020
Time of assessment (00:00-23:59)	09:17 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:17
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

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)	01 SEP 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 10:52
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG

US3182145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 10:17 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 10:17

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

US3182145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 SEP 2020

Collection time (00:00-23:59)

09:47 (24 HR)

Collection date and time (derived)

01 SEP 2020 09:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:24	01 SEP 2020 09:24
Nasopharyngeal Swab 2	No		

US3182145

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 10:48

PC Open Date & Time

01 SEP 2020 10:37

PC Close Date & Time

01 SEP 2020 13:07

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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 98.7 °F

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

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

PC Time Stamp	01 SEP 2020 20:58
PC Open Date & Time	01 SEP 2020 14:02
PC Close Date & Time	02 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:58

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 21:50

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 20:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 19:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:28

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 10:49

PC Open Date & Time

01 SEP 2020 10:37

PC Close Date & Time

01 SEP 2020 13:07

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

01 SEP 2020 20:59

PC Open Date & Time

01 SEP 2020 14:02

PC Close Date & Time

02 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

02 SEP 2020 20:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

03 SEP 2020 20:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

04 SEP 2020 21:50

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

05 SEP 2020 20:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

06 SEP 2020 19:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

07 SEP 2020 20:28

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 10:50
PC Open Date & Time	01 SEP 2020 10:37
PC Close Date & Time	01 SEP 2020 13:07

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 20:59
PC Open Date & Time	01 SEP 2020 14:02
PC Close Date & Time	02 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

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 ☒

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:59
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

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 ☒

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:38
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

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 ☒

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 21:51
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

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EAB) (1725)

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:07
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

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 ☒

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:47
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 20:29
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3182145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:13

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:16:44

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:11:39

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	09:13 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:13
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	115 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

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.

US3182145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	09:29 (24 HR)
Collection date and time (derived)	30 SEP 2020 09:29

US3182145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:11:40

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 OCT 2020 09:43:31
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 18:01:35

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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	21 OCT 2020 10:45:53
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

01 NOV 2020 10:41:18

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 06:40:28
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 09:38:59

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

22 NOV 2020 12:46:49

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

26 NOV 2020 07:14:45

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 00:01:55

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

11 DEC 2020 07:46:51

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

19 DEC 2020 13:17:12

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	24 DEC 2020 00:35:28
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 JAN 2021 17:17:41
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 07:17:50

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 06:32:38
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

21 JAN 2021 00:13:44

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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	28 JAN 2021 01:19:57
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

04 FEB 2021 00:24:14

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 00:02:31
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

18 FEB 2021 00:08:16

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 06:10:18

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

04 MAR 2021 00:09:37

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

11 MAR 2021 02:52:53

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 00:13:15

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

25 MAR 2021 00:32:31

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

01 APR 2021 00:03:31

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

08 APR 2021 00:40:42

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

15 APR 2021 00:19:18

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

22 APR 2021 07:38:17

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Date and time of submission

29 APR 2021 00:05:03

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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="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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 467

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

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

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

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

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

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

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐ 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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3182145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:32:13

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		04 MAR 2021 00:09:51

US3182145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

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

Folder OID	VISIT4
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US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:53:52

Generated On: 09 Jun 2021 15:32:13

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)	08:57 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 08:57
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

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.

US3182145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Mar 2021 20:42:41

Generated On: 09 Jun 2021 15:32:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 FEB 2021

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

16 FEB 2021 09:15

US3182145

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 15:46:20

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 15:46:20

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 20 Mar 2021 20:42:41

Generated On: 09 Jun 2021 15:32:13

Date of Contact	04 JAN 2021
Time of Contact	12:00
Date and Time of Contact (derived)	04 JAN 2021 12:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 JAN 2021	
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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

Symptom Day

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

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Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 19:09:27

Generated On: 09 Jun 2021 15:32:13

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"/>

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 10 Mar 2021 21:46:22

Generated On: 09 Jun 2021 15:32:13

Date of Visit	04 JAN 2021
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	04 JAN 2021
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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 30 Mar 2021 14:52:44

Generated On: 09 Jun 2021 15:32:13

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date 05 JAN 2021

End Date 09 JAN 2021

Oxygen Saturation 92 %

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 30 Mar 2021 14:52:44

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 30 Mar 2021 14:52:44

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 14 Apr 2021 15:42:54

Generated On: 09 Jun 2021 15:32:13

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	06 JAN 2021
Day 5	Yes	08 JAN 2021
Day 7	Yes	10 JAN 2021
Day 9	Yes	12 JAN 2021
Day 14	Yes	17 JAN 2021
Day 21	Yes	24 JAN 2021
Day 28	Yes	01 FEB 2021

US3182145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 JAN 2021
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	04 JAN 2021 12:10
Height (xxx.x)	158.4 cm
Weight (xxx.x)	83.91 kg
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	105 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182145

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 JAN 2021

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

US3182145

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

04 JAN 2021

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 FEB 2021
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 09:20
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	112 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 FEB 2021

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

US3182145

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

01 FEB 2021

US3182145

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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

Folder OID	UNBLND_DECIDE
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US3182145

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

Form: Unblinding

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Date of updated informed consent (<i>dd MMM yyyy</i>)	16 FEB 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

US3182145

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Height	167.8 cm
Weight	83.9 kg
BMI (xxx.x)	29.79738

US3182145

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Height	167.8 cm
Weight	83.9 kg
BMI (xxx.x)	29.79738
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)	08:57 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 08:57
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3182145

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 04:22:25

Generated On: 09 Jun 2021 15:32:13

Height	167.8 cm
Weight	83.9 kg
BMI (xxx.x)	29.79738
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)	10:00 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 10:00
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)	87 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)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3182145

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

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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.

US3182145

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

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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) 09:30 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 09:30

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

What was the frequency of the study treatment dosing? ONCE

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

US3182145

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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)	09:15 (24 HR)
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Collection date and time (derived)	16 FEB 2021 09:15
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US3182145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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)	09:10
Collection Date and Time (derived)	16 FEB 2021 09:10

US3182145

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

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 17:01:44

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 17:01:44

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 17:01:44

Generated On: 09 Jun 2021 15:32:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Mar 2021 17:01:44

Generated On: 09 Jun 2021 15:32:13

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 MAR 2021
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 08:28
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Mar 2021 17:01:44

Generated On: 09 Jun 2021 15:32:13

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 MAR 2021
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 09:20
Temperature (xxx.x)	98.6 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)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3182145

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 17:01:44

Generated On: 09 Jun 2021 15:32:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3182145

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 20 Mar 2021 20:42:41

Generated On: 09 Jun 2021 15:32:13

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 MAR 2021

What was the treatment time? (00:00-23:59) 08:50 (24 HR)

Treatment Date and Time (derived) 16 MAR 2021 08:50

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

US3182145

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 17:01:44

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 14:52:44

Generated On: 09 Jun 2021 15:32:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182145

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 14:52:44

Generated On: 09 Jun 2021 15:32:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182145

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 19:52:26

Generated On: 09 Jun 2021 15:32:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 19:52:26

Generated On: 09 Jun 2021 15:32:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 APR 2021
Time of assessment (<i>00:00-23:59</i>)	08:45 (24 HR)
Vital Signs Date and Time (derived)	14 APR 2021 08:45
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>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	105 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182145

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 19:52:26

Generated On: 09 Jun 2021 15:32:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 APR 2021

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

US3182145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 19:52:26

Generated On: 09 Jun 2021 15:32:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	14 APR 2021
Collection time (<i>00:00-23:59</i>)	09:25 (24 HR)
Collection date and time (derived)	14 APR 2021 09:25

US3182145

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 15:35:08

Generated On: 09 Jun 2021 15:32:13

AEID	USA-US075-2021-MRNA-1273-P30 1000001
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	21 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 15:35:08

Generated On: 09 Jun 2021 15:32:13

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

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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

Yes ☒

No ☐

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

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1999	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE OSTEOARTHRITIS
PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

	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)	05 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	05 AUG 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="radio"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE (SECONDARY TO COVID-19)

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3182145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:22:24

Generated On: 09 Jun 2021 15:32:13

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:32:13

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 ☐

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 20:00:04

Generated On: 09 Jun 2021 15:32:13

SAEID	USA-US075-2021-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 20:00:04

Generated On: 09 Jun 2021 15:32:13

SAEID	USA-US075-2021-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/JAN/2021 18:23
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

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 20:00:04

Generated On: 09 Jun 2021 15:32:13

SAEID	USA-US075-2021-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/FEB/2021 16:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Apr 2021 20:00:04

Generated On: 09 Jun 2021 15:32:13

SAEID	USA-US075-2021-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/MAR/2021 14:43
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

US3182145 (Prod: Rapid Medical Research Inc - ERN-PPDS)

US3182145

Form: Participant Creation

Generated On: 09 Jun 2021 15:32:13

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'US3182145'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Aug 2020 13:34:26

US3182145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:35

US3182145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Aug 2020 13:34:27

US3182145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Clinic (Clinic)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:35

US3182145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'SCRN'	System	04 Aug 2020 14:06:35

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Aug 2020 13:34:27

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '51'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 14:31:00
	(b) (4)	

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'YEARS'	System	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '51'	System	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Male (M)'	Cassie Uminski (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'I'	Cassie Uminski (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4)	07 Aug 2020 14:31:00
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:31:00

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '4 Aug 2020'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Aug 2020'	System	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2020'	System	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Amendment 1 (1)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:48

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Aug 2020 13:34:27

US3182145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'I'	System	04 Aug 2020 14:06:53

US3182145

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:32:13

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:06:53

US3182145

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:32:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:36:24

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:38:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:38:07
Data point term sent to Coder	System	07 Aug 2020 14:37:03
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4)	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 1980'	Cassie Uminski (b) (4)	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 1980'	System	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '1980'	System	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered empty.	System	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered empty.	System	07 Aug 2020 14:36:38

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:39:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:39:13
Data point term sent to Coder	System	07 Aug 2020 14:38:04
User entered 'Hypertension'	Cassie Uminski (b) (4)	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2017'	Cassie Uminski (b) (4)	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2017'	System	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2017'	System	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered empty.	System	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered empty.	System	07 Aug 2020 14:37:51

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:40:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:40:08
Data point term sent to Coder	System	07 Aug 2020 14:39:05
User entered 'Umbilical Hernia'	Cassie Uminski (b) (4)	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2007'	Cassie Uminski	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2007'	Cassie Uminski (b) (4)	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2007'	System	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2007'	System	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2007'	System	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2007'	System	07 Aug 2020 14:38:05

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Umbilical hernia repair, LLT: Umbilical hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:41:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:41:13
Data point term sent to Coder	System	07 Aug 2020 14:40:06
User entered 'Umbilical Hernia Repair'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2007'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2007'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2007'	System	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2007'	System	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2007'	System	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2007'	System	07 Aug 2020 14:39:10

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:17:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:17:12
Data point term sent to Coder	System	07 Aug 2020 14:40:06
User entered 'Torn Left Rotator Cuff'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2009'	Cassie Uminski	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2009'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2009'	System	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2009'	System	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2009'	System	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2009'	System	07 Aug 2020 14:39:25

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:01:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:01:17
Data point term sent to Coder	System	12 Aug 2020 17:59:35
User entered 'Left rotator cuff repair'	Cassie Uminski (b) (4)	12 Aug 2020 17:59:00

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2009'	Cassie Uminski (b) (4)	12 Aug 2020 17:59:00

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	(b) (4)	12 Aug 2020 17:59:00
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	12 Aug 2020 17:59:00
	(b) (4)	

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2009'	Cassie Uminski (b) (4)	12 Aug 2020 17:59:00

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 17:59:00

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2009'	System	12 Aug 2020 17:59:00

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2009'	System	12 Aug 2020 17:59:00

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2009'	System	12 Aug 2020 17:59:00

US3182145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2009'	System	12 Aug 2020 17:59:00

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User closed query 'Per DM CLR: Please specify the location of Osteoarthritis. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 04:56:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 08:04:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 08:04:35
Data point term sent to Coder	System	09 Sep 2020 20:29:26
Query 'Per DM CLR: Please specify the location of Osteoarthritis. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:29:14
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:29:09
User entered 'OSTEOARTHRITIS-Left knee' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:29:09
User opened query 'Per DM CLR: Please specify the location of Osteoarthritis. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:07:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:01:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:01:18
Data point term sent to Coder	System	12 Aug 2020 17:59:36
User entered 'Osteoarthritis'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'un UNK 2009'	Cassie Uminski (b) (4)	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4)	12 Aug 2020 17:59:31
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'Jan 2009'	System	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '2009'	System	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered empty.	System	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered empty.	System	12 Aug 2020 17:59:31

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 14:32:30
	(b) (4)	

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '04 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '09:06'	(b) (4)	07 Aug 2020 14:32:30
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered '04 Aug 2020 09:06'	System	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '167.6' cm	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 14:32:30
DataPoint set to visible.	(b) (4) System	04 Aug 2020 14:06:53

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '87.0' kg	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 14:32:30
DataPoint set to visible.	(b) (4)	
	System	04 Aug 2020 14:06:53

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
Amendment Manager: User entered '30.97214'	System	16 Sep 2020 23:42:09
User entered '31.0'	System	07 Aug 2020 14:32:30
DataPoint set to visible.	System	04 Aug 2020 14:06:53

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'kg/m2'	System	07 Aug 2020 14:32:30
DataPoint set to visible.	System	04 Aug 2020 14:06:53

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 04:56:01
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:29:32
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:29:27
User opened query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 04:53:29
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'bpm'	System	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'breaths/min'	System	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'mmHg'	System	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User entered 'mmHg'	System	07 Aug 2020 14:32:30

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16

US3182145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16

US3182145

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:34:11

US3182145

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:39:32
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:20:59
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:34:11

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:35:34

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:35:34

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

[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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

[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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

[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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'No (N)'	(b) (4)	07 Aug 2020 14:35:34
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4)	07 Aug 2020 14:35:34
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered 'I'	Cassie Uminski	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

[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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

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 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:35:34

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:35:34

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered '0'	Cassie Uminski	07 Aug 2020 14:35:34

US3182145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:29
User entered empty.	(b) (4)	07 Aug 2020 14:35:34
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	07 Aug 2020 14:35:00

US3182145

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '04 Aug 2020'	Cassie Uminski	07 Aug 2020 14:35:00

US3182145

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[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 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Clinic (Clinic)'	Cassie Uminski	07 Aug 2020 14:35:00

US3182145

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'VISIT1'	System	07 Aug 2020 14:35:00

US3182145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Aug 2020 13:54:45

US3182145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:13

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:54:08
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:54:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 13:54:45
User entered '100883' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Aug 2020 13:54:45

US3182145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:13

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Aug 2020 13:54:45

US3182145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:13

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 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:57

US3182145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:13

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 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:57

US3182145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:13

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:57

US3182145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:13

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	Cassie Uminski	07 Aug 2020 14:33:57

US3182145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	Cassie Uminski	07 Aug 2020 14:33:57

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	07 Aug 2020 14:33:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '04 Aug 2020'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '09:06'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '04 Aug 2020 09:06'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '98.1' F	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '80'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'bpm'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '16'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'breaths/min'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '140'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '95'	Cassie Uminski	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '04 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:31:01
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 14:33:23
User entered '10:37'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '04 Aug 2020 10:37'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '97.7' F	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23
	(b) (4)	

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Oral (Oral)'	Cassie Uminski	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23
	(b) (4)	

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '80'	Cassie Uminski	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'bpm'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '16'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'breaths/min'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '140'	Cassie Uminski (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User closed query 'Diastolic Blood Pressure reported is out of range > 100 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)	11 Sep 2020 16:08:22
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:30:21
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		07 Aug 2020 14:33:23
User entered '104'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	07 Aug 2020 14:33:23

US3182145

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	Cassie Uminski	07 Aug 2020 14:34:16

US3182145

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:34:16

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	(b) (4)	
	Amy Maroun (b) (4)	04 Aug 2020 14:07:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

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 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '4 Aug 2020'	Amy Maroun (b) (4)	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '10:02'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '4 Aug 2020 10:02'	System	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Right Arm (RIGHT ARM)'	Amy Maroun (b) (4)	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'ONCE'	System	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 14:07:12

US3182145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:47

US3182145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '04 Aug 2020'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:47

US3182145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '09:50'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:47

US3182145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '04 Aug 2020 09:50'	System	07 Aug 2020 14:34:47

US3182145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:32:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '04 Aug 2020'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:30

US3182145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:30
	(b) (4)	

US3182145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:30

US3182145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '09:35'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:30

US3182145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '04 Aug 2020 09:35'	System	07 Aug 2020 14:34:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:30

US3182145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:30

US3182145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:34:30

US3182145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:13

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered empty.	System	07 Aug 2020 14:34:30

US3182145

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 14:34:51

US3182145

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	07 Aug 2020 14:34:51

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:31:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '155946c3-8dde-460d-b9b9-42113a19d93a' User entered 'Yes (Y)'	System	04 Aug 2020 14:34:11
	System	04 Aug 2020 14:34:11

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:33:31', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '155946c3-8dde-460d-b9b9-42113a19d93a' User entered '97.7'	System	04 Aug 2020 14:34:11
	System	04 Aug 2020 14:34:11

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:33:54', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '155946c3-8dde-460d-b9b9-42113a19d93a'	System	04 Aug 2020 14:34:11
User entered 'No (N)'	System	04 Aug 2020 14:34:11

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:34:08', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '155946c3-8dde-460d-b9b9-42113a19d93a'	System	04 Aug 2020 14:34:11
User entered '04 Aug 2020 10:34'	System	04 Aug 2020 14:34:11

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 10:22'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 12:52'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:32:30', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'f977a74c-40a9-4353-8bd1-e13852e1ed1f' User entered 'Yes (Y)'	System	04 Aug 2020 23:32:52
	System	04 Aug 2020 23:32:52

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:32:37', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'f977a74c-40a9-4353-8bd1-e13852e1ed1f' User entered '98.6'	System	04 Aug 2020 23:32:52
	System	04 Aug 2020 23:32:52

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:32:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'f977a74c-40a9-4353-8bd1-e13852e1ed1f' User entered 'No (N)'	System	04 Aug 2020 23:32:52
	System	04 Aug 2020 23:32:52

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:32:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'f977a74c-40a9-4353-8bd1-e13852e1ed1f' User entered '04 Aug 2020 19:32'	System	04 Aug 2020 23:32:52
	System	04 Aug 2020 23:32:52

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 13:47'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 2'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:24:38', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a017846e-2f64-484f-845e-1ac4c99bcc51'	System	05 Aug 2020 23:25:22
User entered 'Yes (Y)'	System	05 Aug 2020 23:25:22

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:24:45', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a017846e-2f64-484f-845e-1ac4c99bcc51' User entered '98.8'	System	05 Aug 2020 23:25:22
	System	05 Aug 2020 23:25:22

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:24:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a017846e-2f64-484f-845e-1ac4c99bcc51'	System	05 Aug 2020 23:25:22
User entered 'Yes (Y)'	System	05 Aug 2020 23:25:22

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 18:45:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Cassie Uminski (b) (4)	19 Oct 2020 19:03:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:25:06', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a017846e-2f64-484f-845e-1ac4c99bcc51'	(b) (4)	
User entered '1'	System	05 Aug 2020 23:25:22
	System	05 Aug 2020 23:25:22
	System	05 Aug 2020 23:25:22

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:25:06', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a017846e-2f64-484f-845e-1ac4c99bcc51' User entered '0'	System	05 Aug 2020 23:25:22
	System	05 Aug 2020 23:25:22

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:25:20', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a017846e-2f64-484f-845e-1ac4c99bcc51'	System	05 Aug 2020 23:25:22
User entered '05 Aug 2020 19:25'	System	05 Aug 2020 23:25:22

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 3'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:47:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9c082469-5917-4e68-a1da-c590d9a82f26' User entered 'Yes (Y)'	System	06 Aug 2020 23:48:02
	System	06 Aug 2020 23:48:02

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:47:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9c082469-5917-4e68-a1da-c590d9a82f26' User entered '98.0'	System	06 Aug 2020 23:48:02
	System	06 Aug 2020 23:48:02

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:47:54', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9c082469-5917-4e68-a1da-c590d9a82f26'	System	06 Aug 2020 23:48:02
User entered 'No (N)'	System	06 Aug 2020 23:48:02

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:47:59', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9c082469-5917-4e68-a1da-c590d9a82f26' User entered '06 Aug 2020 19:47'	System	06 Aug 2020 23:48:02
	System	06 Aug 2020 23:48:02

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 4'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:04:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e4e65ce3-4208-4c59-b6db-fa933f657356' User entered 'Yes (Y)'	System	07 Aug 2020 21:04:50
	System	07 Aug 2020 21:04:50

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:04:38', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e4e65ce3-4208-4c59-b6db-fa933f657356' User entered '97.2'	System	07 Aug 2020 21:04:50
	System	07 Aug 2020 21:04:50

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:04:42', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e4e65ce3-4208-4c59-b6db-fa933f657356'	System	07 Aug 2020 21:04:50
User entered 'No (N)'	System	07 Aug 2020 21:04:50

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:04:47', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e4e65ce3-4208-4c59-b6db-fa933f657356' User entered '07 Aug 2020 17:04'	System	07 Aug 2020 21:04:50
	System	07 Aug 2020 21:04:50

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 5'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:11', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '146ca31c-d5ff-4b90-b688-1f3e725702c0'	System	08 Aug 2020 22:17:09
User entered 'Yes (Y)'	System	08 Aug 2020 22:17:09

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:17', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '146ca31c-d5ff-4b90-b688-1f3e725702c0' User entered '98.2'	System	08 Aug 2020 22:17:09
	System	08 Aug 2020 22:17:09

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:22', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '146ca31c-d5ff-4b90-b688-1f3e725702c0'	System	08 Aug 2020 22:17:09
User entered 'No (N)'	System	08 Aug 2020 22:17:09

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:26', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '146ca31c-d5ff-4b90-b688-1f3e725702c0' User entered '08 Aug 2020 18:16'	System	08 Aug 2020 22:17:09
	System	08 Aug 2020 22:17:09

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 6'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:49:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '8abd5ef0-853d-4984-a36a-6d669e3ecf17' User entered 'Yes (Y)'	System	09 Aug 2020 21:50:10
	System	09 Aug 2020 21:50:10

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:49:56', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '8abd5ef0-853d-4984-a36a-6d669e3ecf17' User entered '99.0'	System	09 Aug 2020 21:50:10
	System	09 Aug 2020 21:50:10

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '8abd5ef0-853d-4984-a36a-6d669e3ecf17'	System	09 Aug 2020 21:50:10
User entered 'No (N)'	System	09 Aug 2020 21:50:10

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:07', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '8abd5ef0-853d-4984-a36a-6d669e3ecf17' User entered '09 Aug 2020 17:50'	System	09 Aug 2020 21:50:10
	System	09 Aug 2020 21:50:10

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 7'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:19:52', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd9bb3a76-fa85-447d-8a73-3a31b8c325da' User entered 'Yes (Y)'	System	11 Aug 2020 01:20:08
	System	11 Aug 2020 01:20:08

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:19:58', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd9bb3a76-fa85-447d-8a73-3a31b8c325da' User entered '97.7'	System	11 Aug 2020 01:20:08
	System	11 Aug 2020 01:20:08

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:20:01', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd9bb3a76-fa85-447d-8a73-3a31b8c325da' User entered 'No (N)'	System	11 Aug 2020 01:20:08
	System	11 Aug 2020 01:20:08

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:20:06', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd9bb3a76-fa85-447d-8a73-3a31b8c325da' User entered '10 Aug 2020 21:20'	System	11 Aug 2020 01:20:08
	System	11 Aug 2020 01:20:08

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:34:35', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7d4a8295-19f4-45b0-b0bd-d36c0edefe6f' User entered 'None (1)'	System	04 Aug 2020 14:36:04
	System	04 Aug 2020 14:36:04

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:35:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7d4a8295-19f4-45b0-b0bd-d36c0edefe6f' User entered 'No (N)'	System	04 Aug 2020 14:36:04
	System	04 Aug 2020 14:36:04

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:35:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7d4a8295-19f4-45b0-b0bd-d36c0edefe6f' User entered 'No (N)'	System	04 Aug 2020 14:36:04
	System	04 Aug 2020 14:36:04

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:35:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7d4a8295-19f4-45b0-b0bd-d36c0edefe6f' User entered 'None (1)'	System	04 Aug 2020 14:36:04
	System	04 Aug 2020 14:36:04

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:02', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7d4a8295-19f4-45b0-b0bd-d36c0edefe6f' User entered '04 Aug 2020 10:36'	System	04 Aug 2020 14:36:04
	System	04 Aug 2020 14:36:04

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 10:22'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 12:52'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:33:01', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9f97aa09-6df4-4c45-a59a-be69336845b7'	System	04 Aug 2020 23:33:33
User entered 'None (1)'	System	04 Aug 2020 23:33:33

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:33:05', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9f97aa09-6df4-4c45-a59a-be69336845b7'	System	04 Aug 2020 23:33:33
User entered 'No (N)'	System	04 Aug 2020 23:33:33

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:33:12', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9f97aa09-6df4-4c45-a59a-be69336845b7'	System	04 Aug 2020 23:33:33
User entered 'No (N)'	System	04 Aug 2020 23:33:33

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:33:23', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9f97aa09-6df4-4c45-a59a-be69336845b7'	System	04 Aug 2020 23:33:33
User entered 'None (1)'	System	04 Aug 2020 23:33:33

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:33:30', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '9f97aa09-6df4-4c45-a59a-be69336845b7' User entered '04 Aug 2020 19:33'	System	04 Aug 2020 23:33:33
	System	04 Aug 2020 23:33:33

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 13:47'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 2'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:25:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2d4c4bbc-ed75-4bdc-9fc5-44bf44436ed7' User entered 'None (1)'	System	05 Aug 2020 23:26:21
	System	05 Aug 2020 23:26:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:25:54', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2d4c4bbc-ed75-4bdc-9fc5-44bf44436ed7'	System	05 Aug 2020 23:26:21
User entered 'No (N)'	System	05 Aug 2020 23:26:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:25:59', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2d4c4bbc-ed75-4bdc-9fc5-44bf44436ed7'	System	05 Aug 2020 23:26:21
User entered 'No (N)'	System	05 Aug 2020 23:26:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:26:10', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2d4c4bbc-ed75-4bdc-9fc5-44bf44436ed7'	System	05 Aug 2020 23:26:21
User entered 'None (1)'	System	05 Aug 2020 23:26:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:26:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2d4c4bbc-ed75-4bdc-9fc5-44bf44436ed7' User entered '05 Aug 2020 19:26'	System	05 Aug 2020 23:26:21
	System	05 Aug 2020 23:26:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 3'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:48:06', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5cc4d7d0-101a-49ea-b49e-81f1a2ade6b5' User entered 'None (1)'	System	06 Aug 2020 23:48:55
	System	06 Aug 2020 23:48:55

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:48:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5cc4d7d0-101a-49ea-b49e-81f1a2ade6b5' User entered 'No (N)'	System	06 Aug 2020 23:48:55
	System	06 Aug 2020 23:48:55

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:48:35', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5cc4d7d0-101a-49ea-b49e-81f1a2ade6b5' User entered 'No (N)'	System	06 Aug 2020 23:48:55
	System	06 Aug 2020 23:48:55

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:48:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5cc4d7d0-101a-49ea-b49e-81f1a2ade6b5' User entered 'None (1)'	System	06 Aug 2020 23:48:55
	System	06 Aug 2020 23:48:55

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:48:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5cc4d7d0-101a-49ea-b49e-81f1a2ade6b5' User entered '06 Aug 2020 19:48'	System	06 Aug 2020 23:48:55
	System	06 Aug 2020 23:48:55

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 4'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:04:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '66c1257e-4908-4644-9931-874afbb9e03c' User entered 'None (1)'	System	07 Aug 2020 21:05:21
	System	07 Aug 2020 21:05:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:04:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '66c1257e-4908-4644-9931-874afbb9e03c' User entered 'No (N)'	System	07 Aug 2020 21:05:21
	System	07 Aug 2020 21:05:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:01', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '66c1257e-4908-4644-9931-874afbb9e03c' User entered 'No (N)'	System	07 Aug 2020 21:05:21
	System	07 Aug 2020 21:05:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:08', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '66c1257e-4908-4644-9931-874afbb9e03c'	System	07 Aug 2020 21:05:21
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 21:05:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '66c1257e-4908-4644-9931-874afbb9e03c' User entered '07 Aug 2020 17:05'	System	07 Aug 2020 21:05:21
	System	07 Aug 2020 21:05:21

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 5'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:29', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5c6e88f8-d0e3-4260-9139-3144beb49510' User entered 'None (1)'	System	08 Aug 2020 22:17:31
	System	08 Aug 2020 22:17:31

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5c6e88f8-d0e3-4260-9139-3144beb49510' User entered 'No (N)'	System	08 Aug 2020 22:17:31
	System	08 Aug 2020 22:17:31

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5c6e88f8-d0e3-4260-9139-3144beb49510' User entered 'No (N)'	System	08 Aug 2020 22:17:31
	System	08 Aug 2020 22:17:31

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:40', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5c6e88f8-d0e3-4260-9139-3144beb49510' User entered 'None (1)'	System	08 Aug 2020 22:17:31
	System	08 Aug 2020 22:17:31

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5c6e88f8-d0e3-4260-9139-3144beb49510' User entered '08 Aug 2020 18:16'	System	08 Aug 2020 22:17:31
	System	08 Aug 2020 22:17:31

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 6'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:11', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07377136-74c1-4947-82c4-105715632586'	System	09 Aug 2020 21:50:26
User entered 'None (1)'	System	09 Aug 2020 21:50:26

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:15', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07377136-74c1-4947-82c4-105715632586' User entered 'No (N)'	System	09 Aug 2020 21:50:26
	System	09 Aug 2020 21:50:26

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07377136-74c1-4947-82c4-105715632586' User entered 'No (N)'	System	09 Aug 2020 21:50:26
	System	09 Aug 2020 21:50:26

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:22', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07377136-74c1-4947-82c4-105715632586'	System	09 Aug 2020 21:50:26
User entered 'None (1)'	System	09 Aug 2020 21:50:26

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:24', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07377136-74c1-4947-82c4-105715632586' User entered '09 Aug 2020 17:50'	System	09 Aug 2020 21:50:26
	System	09 Aug 2020 21:50:26

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 7'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:20:10', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0832dbcb-5947-44ac-abde-5597a63fe4fb' User entered 'None (1)'	System	11 Aug 2020 01:20:24
	System	11 Aug 2020 01:20:24

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:20:13', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0832dbcb-5947-44ac-abde-5597a63fe4fb' User entered 'No (N)'	System	11 Aug 2020 01:20:24
	System	11 Aug 2020 01:20:24

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:20:16', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0832dbcb-5947-44ac-abde-5597a63fe4fb' User entered 'No (N)'	System	11 Aug 2020 01:20:24
	System	11 Aug 2020 01:20:24

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:20:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0832dbcb-5947-44ac-abde-5597a63fe4fb' User entered 'None (1)'	System	11 Aug 2020 01:20:24
	System	11 Aug 2020 01:20:24

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T21:20:22', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0832dbcb-5947-44ac-abde-5597a63fe4fb' User entered '10 Aug 2020 21:20'	System	11 Aug 2020 01:20:24
	System	11 Aug 2020 01:20:24

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:11', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c8b1f5b8-8abc-4e1c-a04e-8ee87be954dc' User entered 'None (0)'	System	04 Aug 2020 14:36:53
	System	04 Aug 2020 14:36:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c8b1f5b8-8abc-4e1c-a04e-8ee87be954dc' User entered 'None (0)'	System	04 Aug 2020 14:36:53
	System	04 Aug 2020 14:36:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:25', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c8b1f5b8-8abc-4e1c-a04e-8ee87be954dc' User entered 'None (0)'	System	04 Aug 2020 14:36:53
	System	04 Aug 2020 14:36:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:32', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c8b1f5b8-8abc-4e1c-a04e-8ee87be954dc' User entered 'None (0)'	System	04 Aug 2020 14:36:53
	System	04 Aug 2020 14:36:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:37', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c8b1f5b8-8abc-4e1c-a04e-8ee87be954dc' User entered 'None (0)'	System	04 Aug 2020 14:36:53
	System	04 Aug 2020 14:36:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:40', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c8b1f5b8-8abc-4e1c-a04e-8ee87be954dc' User entered 'None (0)'	System	04 Aug 2020 14:36:53
	System	04 Aug 2020 14:36:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:47', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c8b1f5b8-8abc-4e1c-a04e-8ee87be954dc'	System	04 Aug 2020 14:36:53
User entered 'No (N)'	System	04 Aug 2020 14:36:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T10:36:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c8b1f5b8-8abc-4e1c-a04e-8ee87be954dc' User entered '04 Aug 2020 10:36'	System	04 Aug 2020 14:36:53
	System	04 Aug 2020 14:36:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 10:22'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 12:52'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:33:44', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '54473415-c1aa-40b6-b8dc-a4f3e115274f' User entered 'No interference with activity (1)'	System	04 Aug 2020 23:34:46
	System	04 Aug 2020 23:34:46

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:33:59', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '54473415-c1aa-40b6-b8dc-a4f3e115274f' User entered 'None (0)'	System	04 Aug 2020 23:34:46
	System	04 Aug 2020 23:34:46

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:34:09', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '54473415-c1aa-40b6-b8dc-a4f3e115274f' User entered 'None (0)'	System	04 Aug 2020 23:34:46
	System	04 Aug 2020 23:34:46

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:34:15', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '54473415-c1aa-40b6-b8dc-a4f3e115274f' User entered 'None (0)'	System	04 Aug 2020 23:34:46
	System	04 Aug 2020 23:34:46

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:34:20', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '54473415-c1aa-40b6-b8dc-a4f3e115274f' User entered 'None (0)'	System	04 Aug 2020 23:34:46
	System	04 Aug 2020 23:34:46

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:34:25', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '54473415-c1aa-40b6-b8dc-a4f3e115274f' User entered 'None (0)'	System	04 Aug 2020 23:34:46
	System	04 Aug 2020 23:34:46

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:34:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '54473415-c1aa-40b6-b8dc-a4f3e115274f' User entered 'No (N)'	System	04 Aug 2020 23:34:46
	System	04 Aug 2020 23:34:46

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-04T19:34:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '54473415-c1aa-40b6-b8dc-a4f3e115274f' User entered '04 Aug 2020 19:34'	System	04 Aug 2020 23:34:46
	System	04 Aug 2020 23:34:46

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Aug 2020 13:47'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 2'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:26:56', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd93f3214-e188-4a63-8d69-f93ead389497'	System	05 Aug 2020 23:27:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Aug 2020 23:27:45

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:27:01', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd93f3214-e188-4a63-8d69-f93ead389497' User entered 'None (0)'	System	05 Aug 2020 23:27:45
	System	05 Aug 2020 23:27:45

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:27:07', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd93f3214-e188-4a63-8d69-f93ead389497' User entered 'None (0)'	System	05 Aug 2020 23:27:45
	System	05 Aug 2020 23:27:45

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:27:15', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd93f3214-e188-4a63-8d69-f93ead389497' User entered 'None (0)'	System	05 Aug 2020 23:27:45
	System	05 Aug 2020 23:27:45

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:27:19', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd93f3214-e188-4a63-8d69-f93ead389497' User entered 'None (0)'	System	05 Aug 2020 23:27:45
	System	05 Aug 2020 23:27:45

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:27:24', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd93f3214-e188-4a63-8d69-f93ead389497' User entered 'None (0)'	System	05 Aug 2020 23:27:45
	System	05 Aug 2020 23:27:45

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:27:34', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd93f3214-e188-4a63-8d69-f93ead389497'	System	05 Aug 2020 23:27:45
User entered 'No (N)'	System	05 Aug 2020 23:27:45

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-05T19:27:42', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd93f3214-e188-4a63-8d69-f93ead389497'	System	05 Aug 2020 23:27:45
User entered '05 Aug 2020 19:27'	System	05 Aug 2020 23:27:45

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 3'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:49:02', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e3fd666-fee3-4c47-b2cc-fe65e9e03f20'	System	06 Aug 2020 23:49:44
User entered 'No interference with activity (1)'	System	06 Aug 2020 23:49:44

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:49:10', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e3fd666-fee3-4c47-b2cc-fe65e9e03f20' User entered 'None (0)'	System	06 Aug 2020 23:49:44
	System	06 Aug 2020 23:49:44

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:49:16', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e3fd666-fee3-4c47-b2cc-fe65e9e03f20' User entered 'None (0)'	System	06 Aug 2020 23:49:44
	System	06 Aug 2020 23:49:44

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:49:21', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e3fd666-fee3-4c47-b2cc-fe65e9e03f20' User entered 'None (0)'	System	06 Aug 2020 23:49:44
	System	06 Aug 2020 23:49:44

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:49:24', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e3fd666-fee3-4c47-b2cc-fe65e9e03f20' User entered 'None (0)'	System	06 Aug 2020 23:49:44
	System	06 Aug 2020 23:49:44

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:49:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e3fd666-fee3-4c47-b2cc-fe65e9e03f20' User entered 'None (0)'	System	06 Aug 2020 23:49:44
	System	06 Aug 2020 23:49:44

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:49:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e3fd666-fee3-4c47-b2cc-fe65e9e03f20'	System	06 Aug 2020 23:49:44
User entered 'No (N)'	System	06 Aug 2020 23:49:44

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-06T19:49:40', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e3fd666-fee3-4c47-b2cc-fe65e9e03f20' User entered '06 Aug 2020 19:49'	System	06 Aug 2020 23:49:44
	System	06 Aug 2020 23:49:44

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 4'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:26', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be1d600a-928e-4996-adc3-4dadb208c972'	System	07 Aug 2020 21:05:53
User entered 'No interference with activity (1)'	System	07 Aug 2020 21:05:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:31', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be1d600a-928e-4996-adc3-4dadb208c972' User entered 'None (0)'	System	07 Aug 2020 21:05:53
	System	07 Aug 2020 21:05:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:34', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be1d600a-928e-4996-adc3-4dadb208c972' User entered 'None (0)'	System	07 Aug 2020 21:05:53
	System	07 Aug 2020 21:05:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be1d600a-928e-4996-adc3-4dadb208c972' User entered 'None (0)'	System	07 Aug 2020 21:05:53
	System	07 Aug 2020 21:05:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be1d600a-928e-4996-adc3-4dadb208c972' User entered 'None (0)'	System	07 Aug 2020 21:05:53
	System	07 Aug 2020 21:05:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:46', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be1d600a-928e-4996-adc3-4dadb208c972' User entered 'None (0)'	System	07 Aug 2020 21:05:53
	System	07 Aug 2020 21:05:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:49', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be1d600a-928e-4996-adc3-4dadb208c972' User entered 'No (N)'	System	07 Aug 2020 21:05:53
	System	07 Aug 2020 21:05:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-07T17:05:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be1d600a-928e-4996-adc3-4dadb208c972' User entered '07 Aug 2020 17:05'	System	07 Aug 2020 21:05:53
	System	07 Aug 2020 21:05:53

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 5'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:47', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '27ff9914-d0d7-42a2-8453-a06b7b94d4ab' User entered 'None (0)'	System	08 Aug 2020 22:18:12
	System	08 Aug 2020 22:18:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:49', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '27ff9914-d0d7-42a2-8453-a06b7b94d4ab' User entered 'None (0)'	System	08 Aug 2020 22:18:12
	System	08 Aug 2020 22:18:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '27ff9914-d0d7-42a2-8453-a06b7b94d4ab' User entered 'None (0)'	System	08 Aug 2020 22:18:12
	System	08 Aug 2020 22:18:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:55', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '27ff9914-d0d7-42a2-8453-a06b7b94d4ab' User entered 'None (0)'	System	08 Aug 2020 22:18:12
	System	08 Aug 2020 22:18:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:16:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '27ff9914-d0d7-42a2-8453-a06b7b94d4ab' User entered 'None (0)'	System	08 Aug 2020 22:18:12
	System	08 Aug 2020 22:18:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:17:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '27ff9914-d0d7-42a2-8453-a06b7b94d4ab' User entered 'None (0)'	System	08 Aug 2020 22:18:12
	System	08 Aug 2020 22:18:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:17:08', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '27ff9914-d0d7-42a2-8453-a06b7b94d4ab' User entered 'No (N)'	System	08 Aug 2020 22:18:12
	System	08 Aug 2020 22:18:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-08T18:17:12', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '27ff9914-d0d7-42a2-8453-a06b7b94d4ab' User entered '08 Aug 2020 18:17'	System	08 Aug 2020 22:18:12
	System	08 Aug 2020 22:18:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 6'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:32', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b8d2590d-7676-4abb-ac9c-2bda17134f2c' User entered 'None (0)'	System	09 Aug 2020 21:50:58
	System	09 Aug 2020 21:50:58

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b8d2590d-7676-4abb-ac9c-2bda17134f2c' User entered 'None (0)'	System	09 Aug 2020 21:50:58
	System	09 Aug 2020 21:50:58

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b8d2590d-7676-4abb-ac9c-2bda17134f2c' User entered 'None (0)'	System	09 Aug 2020 21:50:58
	System	09 Aug 2020 21:50:58

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:42', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b8d2590d-7676-4abb-ac9c-2bda17134f2c' User entered 'None (0)'	System	09 Aug 2020 21:50:58
	System	09 Aug 2020 21:50:58

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b8d2590d-7676-4abb-ac9c-2bda17134f2c' User entered 'None (0)'	System	09 Aug 2020 21:50:58
	System	09 Aug 2020 21:50:58

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b8d2590d-7676-4abb-ac9c-2bda17134f2c' User entered 'None (0)'	System	09 Aug 2020 21:50:58
	System	09 Aug 2020 21:50:58

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:54', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b8d2590d-7676-4abb-ac9c-2bda17134f2c' User entered 'No (N)'	System	09 Aug 2020 21:50:58
	System	09 Aug 2020 21:50:58

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-09T17:50:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b8d2590d-7676-4abb-ac9c-2bda17134f2c' User entered '09 Aug 2020 17:50'	System	09 Aug 2020 21:50:58
	System	09 Aug 2020 21:50:58

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 7'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T22:38:30', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '11672fbe-453f-48ba-b601-ec2e441f6c0e' User entered 'None (0)'	System	11 Aug 2020 02:38:50
	System	11 Aug 2020 02:38:50

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T22:38:32', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '11672fbe-453f-48ba-b601-ec2e441f6c0e' User entered 'None (0)'	System	11 Aug 2020 02:38:50
	System	11 Aug 2020 02:38:50

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T22:38:34', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '11672fbe-453f-48ba-b601-ec2e441f6c0e' User entered 'None (0)'	System	11 Aug 2020 02:38:50
	System	11 Aug 2020 02:38:50

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T22:38:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '11672fbe-453f-48ba-b601-ec2e441f6c0e' User entered 'None (0)'	System	11 Aug 2020 02:38:50
	System	11 Aug 2020 02:38:50

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T22:38:37', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '11672fbe-453f-48ba-b601-ec2e441f6c0e' User entered 'None (0)'	System	11 Aug 2020 02:38:50
	System	11 Aug 2020 02:38:50

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T22:38:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '11672fbe-453f-48ba-b601-ec2e441f6c0e' User entered 'None (0)'	System	11 Aug 2020 02:38:50
	System	11 Aug 2020 02:38:50

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T22:38:41', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '11672fbe-453f-48ba-b601-ec2e441f6c0e' User entered 'No (N)'	System	11 Aug 2020 02:38:50
	System	11 Aug 2020 02:38:50

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-08-10T22:38:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '11672fbe-453f-48ba-b601-ec2e441f6c0e' User entered '10 Aug 2020 22:38'	System	11 Aug 2020 02:38:50
	System	11 Aug 2020 02:38:50

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:07:12

US3182145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:07:12

(b)

US3182145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered 'Yes (Y)'	Cassie Uminski	14 Aug 2020 12:24:03

US3182145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered '11 Aug 2020'	Cassie Uminski (b) (4)	14 Aug 2020 12:24:03

US3182145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	14 Aug 2020 12:24:03

US3182145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	14 Aug 2020 12:24:03
	(b) (4)	

US3182145

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered 'Yes (Y)'	Cassie Uminski	14 Aug 2020 12:23:53

US3182145

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	14 Aug 2020 12:23:53

US3182145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:15:05

US3182145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered '18 Aug 2020'	Alec Ireland (b) (4)	24 Aug 2020 13:15:05

US3182145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:15:05

US3182145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:15:05

US3182145

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:14:57

US3182145

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	24 Aug 2020 13:14:57

US3182145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:20:49

US3182145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered '25 Aug 2020'	Alec Ireland (b) (4)	26 Aug 2020 18:20:49

US3182145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	26 Aug 2020 18:20:49

US3182145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:20:49

US3182145

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:20:53

US3182145

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	26 Aug 2020 18:20:53

US3182145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	01 Sep 2020 14:20:59

US3182145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '1 Sep 2020'	Brooke Glivar (b) (4)	01 Sep 2020 14:20:59

US3182145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[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 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Clinic (Clinic)'	Brooke Glivar (b) (4)	01 Sep 2020 14:20:59

US3182145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'VISIT2'	System	01 Sep 2020 14:20:59

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45
	(b) (4)	

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '09:17'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '01 Sep 2020 09:17'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '98.3' F	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45
	(b) (4)	

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '73'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'bpm'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '16'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'breaths/min'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '143'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '94'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '10:52'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '01 Sep 2020 10:52'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '97.9' F	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '67'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'bpm'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '16'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'breaths/min'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '144'	Cassie Uminski (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User closed query 'Diastolic Blood Pressure reported is out of range > 100 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)	11 Sep 2020 17:35:41
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:30:42
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		03 Sep 2020 15:39:45
User entered '101'	Cassie Uminski (b) (4) (b) (4)	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	03 Sep 2020 15:39:45

US3182145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	03 Sep 2020 15:40:00

US3182145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:00

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	Brooke Glivar (b) (4)	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

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 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	Brooke Glivar (b) (4)	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '1 Sep 2020'	Brooke Glivar (b) (4)	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '10:17'	Brooke Glivar (b) (4)	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '1 Sep 2020 10:17'	System	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Right Arm (RIGHT ARM)'	Brooke Glivar (b) (4)	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'ONCE'	System	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 14:20:47

US3182145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:25

US3182145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:25

US3182145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '09:47'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:25

US3182145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '01 Sep 2020 09:47'	System	03 Sep 2020 15:40:25

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:32:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:13

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:13
	(b) (4)	

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:13

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '09:24'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:13

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '01 Sep 2020 09:24'	System	03 Sep 2020 15:40:13

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	03 Sep 2020 15:40:13

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	03 Sep 2020 15:40:13
	(b) (4)	

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	Cassie Uminski (b) (4)	03 Sep 2020 15:40:13

US3182145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:13

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered empty.	System	03 Sep 2020 15:40:13

US3182145

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	03 Sep 2020 15:40:29

US3182145

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	03 Sep 2020 15:40:29

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:47:49', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '13d4c500-cd0a-464b-a43c-4e84b42487c6' User entered 'Yes (Y)'	System	01 Sep 2020 14:48:31
	System	01 Sep 2020 14:48:31

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:48:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '13d4c500-cd0a-464b-a43c-4e84b42487c6' User entered '97.9'	System	01 Sep 2020 14:48:31
	System	01 Sep 2020 14:48:31

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:48:24', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '13d4c500-cd0a-464b-a43c-4e84b42487c6' User entered 'No (N)'	System	01 Sep 2020 14:48:31
	System	01 Sep 2020 14:48:31

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:48:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '13d4c500-cd0a-464b-a43c-4e84b42487c6' User entered '01 Sep 2020 10:48'	System	01 Sep 2020 14:48:31
	System	01 Sep 2020 14:48:31

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 10:37'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:58:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '132fccf9-22cb-4168-a37a-25ce7793a099'	System	02 Sep 2020 00:58:53
User entered 'Yes (Y)'	System	02 Sep 2020 00:58:53

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:58:45', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '132fccf9-22cb-4168-a37a-25ce7793a099' User entered '98.7'	System	02 Sep 2020 00:58:53
	System	02 Sep 2020 00:58:53

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:58:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '132fccf9-22cb-4168-a37a-25ce7793a099'	System	02 Sep 2020 00:58:53
User entered 'No (N)'	System	02 Sep 2020 00:58:53

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:58:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '132fccf9-22cb-4168-a37a-25ce7793a099'	System	02 Sep 2020 00:58:53
User entered '01 Sep 2020 20:58'	System	02 Sep 2020 00:58:53

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 14:02'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 2'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:58:40', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c6161dfc-5ed8-4ba0-a5a6-5f9d3b56cb90' User entered 'Yes (Y)'	System	03 Sep 2020 00:58:52
	System	03 Sep 2020 00:58:52

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:58:44', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c6161dfc-5ed8-4ba0-a5a6-5f9d3b56cb90' User entered '98.0'	System	03 Sep 2020 00:58:52
	System	03 Sep 2020 00:58:52

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:58:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c6161dfc-5ed8-4ba0-a5a6-5f9d3b56cb90'	System	03 Sep 2020 00:58:52
User entered 'No (N)'	System	03 Sep 2020 00:58:52

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:58:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c6161dfc-5ed8-4ba0-a5a6-5f9d3b56cb90' User entered '02 Sep 2020 20:58'	System	03 Sep 2020 00:58:52
	System	03 Sep 2020 00:58:52

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 3'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:12', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7f658b52-10e1-4d50-8859-df90553ba23c' User entered 'Yes (Y)'	System	04 Sep 2020 00:37:26
	System	04 Sep 2020 00:37:26

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:17', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7f658b52-10e1-4d50-8859-df90553ba23c' User entered '98.9'	System	04 Sep 2020 00:37:26
	System	04 Sep 2020 00:37:26

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:22', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7f658b52-10e1-4d50-8859-df90553ba23c'	System	04 Sep 2020 00:37:26
User entered 'No (N)'	System	04 Sep 2020 00:37:26

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:25', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7f658b52-10e1-4d50-8859-df90553ba23c'	System	04 Sep 2020 00:37:26
User entered '03 Sep 2020 20:37'	System	04 Sep 2020 00:37:26

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 4'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:10', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e3a5aaf0-afa1-44ab-9cb8-8433deddf9e4' User entered 'Yes (Y)'	System	05 Sep 2020 01:50:33
	System	05 Sep 2020 01:50:33

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:15', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e3a5aaf0-afa1-44ab-9cb8-8433deddf9e4' User entered '97.1'	System	05 Sep 2020 01:50:33
	System	05 Sep 2020 01:50:33

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:20', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e3a5aaf0-afa1-44ab-9cb8-8433deddf9e4' User entered 'No (N)'	System	05 Sep 2020 01:50:33
	System	05 Sep 2020 01:50:33

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:30', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e3a5aaf0-afa1-44ab-9cb8-8433deddf9e4' User entered '04 Sep 2020 21:50'	System	05 Sep 2020 01:50:33
	System	05 Sep 2020 01:50:33

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 5'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:06:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a05bfd61-cfb7-4685-a37c-691d34d1f130' User entered 'Yes (Y)'	System	06 Sep 2020 00:06:56
	System	06 Sep 2020 00:06:56

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:06:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a05bfd61-cfb7-4685-a37c-691d34d1f130' User entered '98.1'	System	06 Sep 2020 00:06:56
	System	06 Sep 2020 00:06:56

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:06:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a05bfd61-cfb7-4685-a37c-691d34d1f130'	System	06 Sep 2020 00:06:56
User entered 'No (N)'	System	06 Sep 2020 00:06:56

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:06:54', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a05bfd61-cfb7-4685-a37c-691d34d1f130'	System	06 Sep 2020 00:06:56
User entered '05 Sep 2020 20:06'	System	06 Sep 2020 00:06:56

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 6'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:22', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6e0118ae-c260-471a-90ac-0b276d66cb1e' User entered 'Yes (Y)'	System	06 Sep 2020 23:47:32
	System	06 Sep 2020 23:47:32

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:26', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6e0118ae-c260-471a-90ac-0b276d66cb1e' User entered '98.3'	System	06 Sep 2020 23:47:32
	System	06 Sep 2020 23:47:32

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6e0118ae-c260-471a-90ac-0b276d66cb1e' User entered 'No (N)'	System	06 Sep 2020 23:47:32
	System	06 Sep 2020 23:47:32

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:30', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6e0118ae-c260-471a-90ac-0b276d66cb1e' User entered '06 Sep 2020 19:47'	System	06 Sep 2020 23:47:32
	System	06 Sep 2020 23:47:32

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 7'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:26', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '76f28bad-e62b-4048-859b-ff6cdc03f0e9' User entered 'Yes (Y)'	System	08 Sep 2020 00:28:37
	System	08 Sep 2020 00:28:37

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:31', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '76f28bad-e62b-4048-859b-ff6cdc03f0e9' User entered '99.0'	System	08 Sep 2020 00:28:37
	System	08 Sep 2020 00:28:37

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '76f28bad-e62b-4048-859b-ff6cdc03f0e9' User entered 'No (N)'	System	08 Sep 2020 00:28:37
	System	08 Sep 2020 00:28:37

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:35', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '76f28bad-e62b-4048-859b-ff6cdc03f0e9' User entered '07 Sep 2020 20:28'	System	08 Sep 2020 00:28:37
	System	08 Sep 2020 00:28:37

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:14', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '032cd1c3-6d99-45cb-8461-ac2290b43c97'	System	01 Sep 2020 14:49:38
User entered 'None (1)'	System	01 Sep 2020 14:49:38

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '032cd1c3-6d99-45cb-8461-ac2290b43c97' User entered 'No (N)'	System	01 Sep 2020 14:49:38
	System	01 Sep 2020 14:49:38

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:22', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '032cd1c3-6d99-45cb-8461-ac2290b43c97' User entered 'No (N)'	System	01 Sep 2020 14:49:38
	System	01 Sep 2020 14:49:38

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:29', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '032cd1c3-6d99-45cb-8461-ac2290b43c97'	System	01 Sep 2020 14:49:38
User entered 'None (1)'	System	01 Sep 2020 14:49:38

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '032cd1c3-6d99-45cb-8461-ac2290b43c97'	System	01 Sep 2020 14:49:38
User entered '01 Sep 2020 10:49'	System	01 Sep 2020 14:49:38

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 10:37'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:58:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '659a8fa0-bf8d-4663-862f-e339b513c965'	System	02 Sep 2020 00:59:23
User entered 'None (1)'	System	02 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '659a8fa0-bf8d-4663-862f-e339b513c965'	System	02 Sep 2020 00:59:23
User entered 'No (N)'	System	02 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:10', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '659a8fa0-bf8d-4663-862f-e339b513c965' User entered 'No (N)'	System	02 Sep 2020 00:59:23
	System	02 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:17', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '659a8fa0-bf8d-4663-862f-e339b513c965'	System	02 Sep 2020 00:59:23
User entered 'None (1)'	System	02 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:20', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '659a8fa0-bf8d-4663-862f-e339b513c965'	System	02 Sep 2020 00:59:23
User entered '01 Sep 2020 20:59'	System	02 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 14:02'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 2'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5f47eac3-732d-45af-b452-751be306a893'	System	03 Sep 2020 00:59:23
User entered 'None (1)'	System	03 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:04', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5f47eac3-732d-45af-b452-751be306a893'	System	03 Sep 2020 00:59:23
User entered 'No (N)'	System	03 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:07', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5f47eac3-732d-45af-b452-751be306a893'	System	03 Sep 2020 00:59:23
User entered 'No (N)'	System	03 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:16', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5f47eac3-732d-45af-b452-751be306a893'	System	03 Sep 2020 00:59:23
User entered 'None (1)'	System	03 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5f47eac3-732d-45af-b452-751be306a893' User entered '02 Sep 2020 20:59'	System	03 Sep 2020 00:59:23
	System	03 Sep 2020 00:59:23

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 3'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:31', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'dcf55c5b-051d-4e23-b902-0267f4363c73'	System	04 Sep 2020 00:37:43
User entered 'None (1)'	System	04 Sep 2020 00:37:43

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:34', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'dcf55c5b-051d-4e23-b902-0267f4363c73'	System	04 Sep 2020 00:37:43
User entered 'No (N)'	System	04 Sep 2020 00:37:43

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'dcf55c5b-051d-4e23-b902-0267f4363c73' User entered 'No (N)'	System	04 Sep 2020 00:37:43
	System	04 Sep 2020 00:37:43

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:38', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'dcf55c5b-051d-4e23-b902-0267f4363c73'	System	04 Sep 2020 00:37:43
User entered 'None (1)'	System	04 Sep 2020 00:37:43

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:41', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'dcf55c5b-051d-4e23-b902-0267f4363c73' User entered '03 Sep 2020 20:37'	System	04 Sep 2020 00:37:43
	System	04 Sep 2020 00:37:43

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 4'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '99ed669b-8eee-4c15-a7d8-8eda65cbc597'	System	05 Sep 2020 01:50:45
User entered 'None (1)'	System	05 Sep 2020 01:50:45

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '99ed669b-8eee-4c15-a7d8-8eda65cbc597'	System	05 Sep 2020 01:50:45
User entered 'No (N)'	System	05 Sep 2020 01:50:45

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:38', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '99ed669b-8eee-4c15-a7d8-8eda65cbc597' User entered 'No (N)'	System	05 Sep 2020 01:50:45
	System	05 Sep 2020 01:50:45

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:40', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '99ed669b-8eee-4c15-a7d8-8eda65cbc597'	System	05 Sep 2020 01:50:45
User entered 'None (1)'	System	05 Sep 2020 01:50:45

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '99ed669b-8eee-4c15-a7d8-8eda65cbc597'	System	05 Sep 2020 01:50:45
User entered '04 Sep 2020 21:50'	System	05 Sep 2020 01:50:45

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 5'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:06:58', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c2394741-fe44-45df-bb64-f0ad73ddc4a8'	System	06 Sep 2020 00:07:12
User entered 'None (1)'	System	06 Sep 2020 00:07:12

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:01', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c2394741-fe44-45df-bb64-f0ad73ddc4a8'	System	06 Sep 2020 00:07:12
User entered 'No (N)'	System	06 Sep 2020 00:07:12

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:04', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c2394741-fe44-45df-bb64-f0ad73ddc4a8'	System	06 Sep 2020 00:07:12
User entered 'No (N)'	System	06 Sep 2020 00:07:12

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:06', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c2394741-fe44-45df-bb64-f0ad73ddc4a8' User entered 'None (1)'	System	06 Sep 2020 00:07:12
	System	06 Sep 2020 00:07:12

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:09', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c2394741-fe44-45df-bb64-f0ad73ddc4a8' User entered '05 Sep 2020 20:07'	System	06 Sep 2020 00:07:12
	System	06 Sep 2020 00:07:12

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 6'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:34', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0cc02654-83bd-465d-baa6-fd723e0c7f21'	System	06 Sep 2020 23:47:44
User entered 'None (1)'	System	06 Sep 2020 23:47:44

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0cc02654-83bd-465d-baa6-fd723e0c7f21' User entered 'No (N)'	System	06 Sep 2020 23:47:44
	System	06 Sep 2020 23:47:44

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:38', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0cc02654-83bd-465d-baa6-fd723e0c7f21' User entered 'No (N)'	System	06 Sep 2020 23:47:44
	System	06 Sep 2020 23:47:44

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:40', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0cc02654-83bd-465d-baa6-fd723e0c7f21' User entered 'None (1)'	System	06 Sep 2020 23:47:44
	System	06 Sep 2020 23:47:44

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '0cc02654-83bd-465d-baa6-fd723e0c7f21' User entered '06 Sep 2020 19:47'	System	06 Sep 2020 23:47:44
	System	06 Sep 2020 23:47:44

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 7'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6cd1558b-492c-458d-b406-7ad3818a9820'	System	08 Sep 2020 00:28:50
User entered 'None (1)'	System	08 Sep 2020 00:28:50

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:41', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6cd1558b-492c-458d-b406-7ad3818a9820' User entered 'No (N)'	System	08 Sep 2020 00:28:50
	System	08 Sep 2020 00:28:50

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6cd1558b-492c-458d-b406-7ad3818a9820' User entered 'No (N)'	System	08 Sep 2020 00:28:50
	System	08 Sep 2020 00:28:50

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:44', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6cd1558b-492c-458d-b406-7ad3818a9820'	System	08 Sep 2020 00:28:50
User entered 'None (1)'	System	08 Sep 2020 00:28:50

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:46', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6cd1558b-492c-458d-b406-7ad3818a9820' User entered '07 Sep 2020 20:28'	System	08 Sep 2020 00:28:50
	System	08 Sep 2020 00:28:50

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:38', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07440948-aec2-4d68-aa82-4528d726ef78' User entered 'None (0)'	System	01 Sep 2020 14:50:08
	System	01 Sep 2020 14:50:08

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:44', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07440948-aec2-4d68-aa82-4528d726ef78' User entered 'None (0)'	System	01 Sep 2020 14:50:08
	System	01 Sep 2020 14:50:08

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:47', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07440948-aec2-4d68-aa82-4528d726ef78' User entered 'None (0)'	System	01 Sep 2020 14:50:08
	System	01 Sep 2020 14:50:08

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07440948-aec2-4d68-aa82-4528d726ef78' User entered 'None (0)'	System	01 Sep 2020 14:50:08
	System	01 Sep 2020 14:50:08

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07440948-aec2-4d68-aa82-4528d726ef78' User entered 'None (0)'	System	01 Sep 2020 14:50:08
	System	01 Sep 2020 14:50:08

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:49:56', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07440948-aec2-4d68-aa82-4528d726ef78' User entered 'None (0)'	System	01 Sep 2020 14:50:08
	System	01 Sep 2020 14:50:08

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:50:02', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07440948-aec2-4d68-aa82-4528d726ef78' User entered 'No (N)'	System	01 Sep 2020 14:50:08
	System	01 Sep 2020 14:50:08

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T10:50:05', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '07440948-aec2-4d68-aa82-4528d726ef78' User entered '01 Sep 2020 10:50'	System	01 Sep 2020 14:50:08
	System	01 Sep 2020 14:50:08

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 10:37'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:23', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e7462a0-7a3b-49e9-b3db-c9fe42c26622' User entered 'None (0)'	System	02 Sep 2020 00:59:45
	System	02 Sep 2020 00:59:45

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:26', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e7462a0-7a3b-49e9-b3db-c9fe42c26622' User entered 'None (0)'	System	02 Sep 2020 00:59:45
	System	02 Sep 2020 00:59:45

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e7462a0-7a3b-49e9-b3db-c9fe42c26622' User entered 'None (0)'	System	02 Sep 2020 00:59:45
	System	02 Sep 2020 00:59:45

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:31', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e7462a0-7a3b-49e9-b3db-c9fe42c26622' User entered 'None (0)'	System	02 Sep 2020 00:59:45
	System	02 Sep 2020 00:59:45

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:34', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e7462a0-7a3b-49e9-b3db-c9fe42c26622' User entered 'None (0)'	System	02 Sep 2020 00:59:45
	System	02 Sep 2020 00:59:45

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e7462a0-7a3b-49e9-b3db-c9fe42c26622' User entered 'None (0)'	System	02 Sep 2020 00:59:45
	System	02 Sep 2020 00:59:45

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:41', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e7462a0-7a3b-49e9-b3db-c9fe42c26622' User entered 'No (N)'	System	02 Sep 2020 00:59:45
	System	02 Sep 2020 00:59:45

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-01T20:59:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2e7462a0-7a3b-49e9-b3db-c9fe42c26622'	System	02 Sep 2020 00:59:45
User entered '01 Sep 2020 20:59'	System	02 Sep 2020 00:59:45

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '01 Sep 2020 14:02'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 2'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:21', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'ccf4be5f-6433-42eb-8d4c-3e8fcf980e21' User entered 'None (0)'	System	03 Sep 2020 00:59:38
	System	03 Sep 2020 00:59:38

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:23', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'ccf4be5f-6433-42eb-8d4c-3e8fcf980e21' User entered 'None (0)'	System	03 Sep 2020 00:59:38
	System	03 Sep 2020 00:59:38

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:25', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'ccf4be5f-6433-42eb-8d4c-3e8fcf980e21' User entered 'None (0)'	System	03 Sep 2020 00:59:38
	System	03 Sep 2020 00:59:38

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'ccf4be5f-6433-42eb-8d4c-3e8fcf980e21' User entered 'None (0)'	System	03 Sep 2020 00:59:38
	System	03 Sep 2020 00:59:38

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:30', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'ccf4be5f-6433-42eb-8d4c-3e8fcf980e21' User entered 'None (0)'	System	03 Sep 2020 00:59:38
	System	03 Sep 2020 00:59:38

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:32', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'ccf4be5f-6433-42eb-8d4c-3e8fcf980e21' User entered 'None (0)'	System	03 Sep 2020 00:59:38
	System	03 Sep 2020 00:59:38

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:34', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'ccf4be5f-6433-42eb-8d4c-3e8fcf980e21' User entered 'No (N)'	System	03 Sep 2020 00:59:38
	System	03 Sep 2020 00:59:38

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-02T20:59:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'ccf4be5f-6433-42eb-8d4c-3e8fcf980e21' User entered '02 Sep 2020 20:59'	System	03 Sep 2020 00:59:38
	System	03 Sep 2020 00:59:38

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 3'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '697bf3cf-c233-4ef4-a267-06b29a7e9342'	System	04 Sep 2020 00:38:06
User entered 'No interference with activity (1)'	System	04 Sep 2020 00:38:06

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '697bf3cf-c233-4ef4-a267-06b29a7e9342' User entered 'None (0)'	System	04 Sep 2020 00:38:06
	System	04 Sep 2020 00:38:06

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '697bf3cf-c233-4ef4-a267-06b29a7e9342'	System	04 Sep 2020 00:38:06
User entered 'None (0)'	System	04 Sep 2020 00:38:06

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:55', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '697bf3cf-c233-4ef4-a267-06b29a7e9342' User entered 'None (0)'	System	04 Sep 2020 00:38:06
	System	04 Sep 2020 00:38:06

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '697bf3cf-c233-4ef4-a267-06b29a7e9342'	System	04 Sep 2020 00:38:06
User entered 'None (0)'	System	04 Sep 2020 00:38:06

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:37:59', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '697bf3cf-c233-4ef4-a267-06b29a7e9342'	System	04 Sep 2020 00:38:06
User entered 'None (0)'	System	04 Sep 2020 00:38:06

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:38:01', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '697bf3cf-c233-4ef4-a267-06b29a7e9342'	System	04 Sep 2020 00:38:06
User entered 'No (N)'	System	04 Sep 2020 00:38:06

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-03T20:38:02', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '697bf3cf-c233-4ef4-a267-06b29a7e9342'	System	04 Sep 2020 00:38:06
User entered '03 Sep 2020 20:38'	System	04 Sep 2020 00:38:06

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 4'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be33015b-dc89-46a3-81c6-1e3437b03218'	System	05 Sep 2020 01:51:16
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:51:16

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be33015b-dc89-46a3-81c6-1e3437b03218' User entered 'None (0)'	System	05 Sep 2020 01:51:16
	System	05 Sep 2020 01:51:16

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be33015b-dc89-46a3-81c6-1e3437b03218' User entered 'None (0)'	System	05 Sep 2020 01:51:16
	System	05 Sep 2020 01:51:16

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:55', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be33015b-dc89-46a3-81c6-1e3437b03218' User entered 'None (0)'	System	05 Sep 2020 01:51:16
	System	05 Sep 2020 01:51:16

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be33015b-dc89-46a3-81c6-1e3437b03218' User entered 'None (0)'	System	05 Sep 2020 01:51:16
	System	05 Sep 2020 01:51:16

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:50:59', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be33015b-dc89-46a3-81c6-1e3437b03218' User entered 'None (0)'	System	05 Sep 2020 01:51:16
	System	05 Sep 2020 01:51:16

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:51:03', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be33015b-dc89-46a3-81c6-1e3437b03218' User entered 'No (N)'	System	05 Sep 2020 01:51:16
	System	05 Sep 2020 01:51:16

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-04T21:51:14', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'be33015b-dc89-46a3-81c6-1e3437b03218' User entered '04 Sep 2020 21:51'	System	05 Sep 2020 01:51:16
	System	05 Sep 2020 01:51:16

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 5'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:12', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'df28e2d5-c710-45e2-a35b-31a8c2a56476' User entered 'None (0)'	System	06 Sep 2020 00:07:31
	System	06 Sep 2020 00:07:31

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:14', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'df28e2d5-c710-45e2-a35b-31a8c2a56476' User entered 'None (0)'	System	06 Sep 2020 00:07:31
	System	06 Sep 2020 00:07:31

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:16', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'df28e2d5-c710-45e2-a35b-31a8c2a56476' User entered 'None (0)'	System	06 Sep 2020 00:07:31
	System	06 Sep 2020 00:07:31

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'df28e2d5-c710-45e2-a35b-31a8c2a56476' User entered 'None (0)'	System	06 Sep 2020 00:07:31
	System	06 Sep 2020 00:07:31

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:20', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'df28e2d5-c710-45e2-a35b-31a8c2a56476' User entered 'None (0)'	System	06 Sep 2020 00:07:31
	System	06 Sep 2020 00:07:31

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:22', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'df28e2d5-c710-45e2-a35b-31a8c2a56476' User entered 'None (0)'	System	06 Sep 2020 00:07:31
	System	06 Sep 2020 00:07:31

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:25', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'df28e2d5-c710-45e2-a35b-31a8c2a56476' User entered 'No (N)'	System	06 Sep 2020 00:07:31
	System	06 Sep 2020 00:07:31

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-05T20:07:27', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'df28e2d5-c710-45e2-a35b-31a8c2a56476' User entered '05 Sep 2020 20:07'	System	06 Sep 2020 00:07:31
	System	06 Sep 2020 00:07:31

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 6'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:47', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fb93e301-c2f8-4a38-9629-5e9d33258a35' User entered 'None (0)'	System	06 Sep 2020 23:48:01
	System	06 Sep 2020 23:48:01

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:48', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fb93e301-c2f8-4a38-9629-5e9d33258a35' User entered 'None (0)'	System	06 Sep 2020 23:48:01
	System	06 Sep 2020 23:48:01

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fb93e301-c2f8-4a38-9629-5e9d33258a35' User entered 'None (0)'	System	06 Sep 2020 23:48:01
	System	06 Sep 2020 23:48:01

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:52', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fb93e301-c2f8-4a38-9629-5e9d33258a35' User entered 'None (0)'	System	06 Sep 2020 23:48:01
	System	06 Sep 2020 23:48:01

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fb93e301-c2f8-4a38-9629-5e9d33258a35' User entered 'None (0)'	System	06 Sep 2020 23:48:01
	System	06 Sep 2020 23:48:01

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:55', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fb93e301-c2f8-4a38-9629-5e9d33258a35' User entered 'None (0)'	System	06 Sep 2020 23:48:01
	System	06 Sep 2020 23:48:01

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fb93e301-c2f8-4a38-9629-5e9d33258a35' User entered 'No (N)'	System	06 Sep 2020 23:48:01
	System	06 Sep 2020 23:48:01

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-06T19:47:59', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fb93e301-c2f8-4a38-9629-5e9d33258a35' User entered '06 Sep 2020 19:47'	System	06 Sep 2020 23:48:01
	System	06 Sep 2020 23:48:01

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	01 Sep 2020 14:20:47
User entered 'Day 7'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '01e6df2e-9aee-4832-b3f3-3b7e7a05e285' User entered 'None (0)'	System	08 Sep 2020 00:29:15
	System	08 Sep 2020 00:29:15

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:56', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '01e6df2e-9aee-4832-b3f3-3b7e7a05e285' User entered 'None (0)'	System	08 Sep 2020 00:29:15
	System	08 Sep 2020 00:29:15

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:58', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '01e6df2e-9aee-4832-b3f3-3b7e7a05e285' User entered 'None (0)'	System	08 Sep 2020 00:29:15
	System	08 Sep 2020 00:29:15

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:28:59', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '01e6df2e-9aee-4832-b3f3-3b7e7a05e285' User entered 'None (0)'	System	08 Sep 2020 00:29:15
	System	08 Sep 2020 00:29:15

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:29:01', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '01e6df2e-9aee-4832-b3f3-3b7e7a05e285' User entered 'None (0)'	System	08 Sep 2020 00:29:15
	System	08 Sep 2020 00:29:15

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:29:03', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '01e6df2e-9aee-4832-b3f3-3b7e7a05e285' User entered 'None (0)'	System	08 Sep 2020 00:29:15
	System	08 Sep 2020 00:29:15

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:29:07', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '01e6df2e-9aee-4832-b3f3-3b7e7a05e285'	System	08 Sep 2020 00:29:15
User entered 'No (N)'	System	08 Sep 2020 00:29:15

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-09-07T20:29:12', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '01e6df2e-9aee-4832-b3f3-3b7e7a05e285' User entered '07 Sep 2020 20:29'	System	08 Sep 2020 00:29:15
	System	08 Sep 2020 00:29:15

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:20:47

US3182145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:20:47

US3182145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:47:12

US3182145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered '8 Sep 2020'	Alec Ireland (b) (4)	09 Sep 2020 17:47:12

US3182145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:47:12

US3182145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:13
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:47:12

US3182145

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:16:44
User entered 'Yes (Y)'	Alec Ireland	09 Sep 2020 17:47:16

US3182145

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	09 Sep 2020 17:47:16

US3182145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:46:34

US3182145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '15 Sep 2020'	Alec Ireland (b) (4)	16 Sep 2020 17:46:34

US3182145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:46:34

US3182145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:46:34

US3182145

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:46:27

US3182145

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	16 Sep 2020 17:46:27

US3182145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:39:04

US3182145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '22 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:39:04

US3182145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:39:04

US3182145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:39:04

US3182145

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:39:09

US3182145

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	24 Sep 2020 16:39:09

US3182145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	02 Oct 2020 18:13:42

US3182145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '30 Sep 2020'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:42

US3182145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[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 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:42

US3182145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'VISIT3'	System	02 Oct 2020 18:13:42

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '30 Sep 2020'	Cassie Uminski (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '09:13'	Cassie Uminski (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '30 Sep 2020 09:13'	System	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '98.3' F	Cassie Uminski (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	Cassie Uminski (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '81'	Cassie Uminski (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'bpm'	System	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '15'	Cassie Uminski (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'breaths/min'	System	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '157'	Cassie Uminski (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
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)	17 Oct 2020 10:45:15
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	17 Oct 2020 10:45:13
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).	Cassie Uminski (b) (4) (b) (4)	09 Oct 2020 13:03:43
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Cassie Uminski (b) (4) (b) (4)	09 Oct 2020 13:03:39
User opened query 'Diastolic Blood Pressure reported System 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).		02 Oct 2020 18:14:04
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Oct 2020 18:14:04
User entered '115'	Cassie Uminski (b) (4) (b) (4)	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'mmHg'	System	02 Oct 2020 18:14:04

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14

US3182145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14

US3182145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'No (N)'	Cassie Uminski	02 Oct 2020 18:15:35

US3182145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered empty.	Cassie Uminski (b) (4)	02 Oct 2020 18:15:35

US3182145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	02 Oct 2020 18:15:43

US3182145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '30 Sep 2020'	Cassie Uminski (b) (4)	02 Oct 2020 18:15:43

US3182145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered '09:29'	Cassie Uminski (b) (4)	02 Oct 2020 18:15:43

US3182145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered '30 Sep 2020 09:29'	System	02 Oct 2020 18:15:43

US3182145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:11:40
User entered 'Yes (Y)'	Cassie Uminski	02 Oct 2020 18:15:51

US3182145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	02 Oct 2020 18:15:51

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 64'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-05T09:43:08', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '427e6a93-701d-4aa0-8bec-de38d8e85fe7'	System	05 Oct 2020 13:43:35
User entered 'No (N)'	System	05 Oct 2020 13:43:35

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-05T09:43:11', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '427e6a93-701d-4aa0-8bec-de38d8e85fe7'	System	05 Oct 2020 13:43:35
User entered 'No (N)'	System	05 Oct 2020 13:43:35

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-05T09:43:31', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '427e6a93-701d-4aa0-8bec-de38d8e85fe7' User entered '05 Oct 2020 09:43:31'	System	05 Oct 2020 13:43:35
	System	05 Oct 2020 13:43:35

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 71'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-13T18:01:21', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '399ee264-4ef8-460f-9e29-1299dcc861e6'	System	13 Oct 2020 22:01:39
User entered 'No (N)'	System	13 Oct 2020 22:01:39

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-13T18:01:26', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '399ee264-4ef8-460f-9e29-1299dcc861e6'	System	13 Oct 2020 22:01:39
User entered 'No (N)'	System	13 Oct 2020 22:01:39

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-13T18:01:35', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '399ee264-4ef8-460f-9e29-1299dcc861e6' User entered '13 Oct 2020 18:01:35'	System	13 Oct 2020 22:01:39
	System	13 Oct 2020 22:01:39

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 78'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-21T10:45:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '48e01a89-9973-4b05-8ff6-32a3edd3fc79'	System	21 Oct 2020 14:45:55
User entered 'No (N)'	System	21 Oct 2020 14:45:55

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-21T10:45:44', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '48e01a89-9973-4b05-8ff6-32a3edd3fc79'	System	21 Oct 2020 14:45:55
User entered 'No (N)'	System	21 Oct 2020 14:45:55

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-10-21T10:45:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '48e01a89-9973-4b05-8ff6-32a3edd3fc79' User entered '21 Oct 2020 10:45:53'	System	21 Oct 2020 14:45:55
	System	21 Oct 2020 14:45:55

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 92'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-01T10:41:10', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd0a4470a-ace2-4f08-a4d2-3e7a036236bc' User entered 'No (N)'	System	01 Nov 2020 15:41:20
	System	01 Nov 2020 15:41:20

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-01T10:41:13', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd0a4470a-ace2-4f08-a4d2-3e7a036236bc' User entered 'No (N)'	System	01 Nov 2020 15:41:20
	System	01 Nov 2020 15:41:20

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-01T10:41:18', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd0a4470a-ace2-4f08-a4d2-3e7a036236bc' User entered '01 Nov 2020 10:41:18'	System	01 Nov 2020 15:41:20
	System	01 Nov 2020 15:41:20

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 99'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-08T06:40:14', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5db1824d-1e75-4f26-a013-69179947335b' User entered 'No (N)'	System	08 Nov 2020 11:40:30
	System	08 Nov 2020 11:40:30

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-08T06:40:23', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5db1824d-1e75-4f26-a013-69179947335b' User entered 'No (N)'	System	08 Nov 2020 11:40:30
	System	08 Nov 2020 11:40:30

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-08T06:40:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '5db1824d-1e75-4f26-a013-69179947335b' User entered '08 Nov 2020 06:40:28'	System	08 Nov 2020 11:40:30
	System	08 Nov 2020 11:40:30

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered 'Day 106'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-15T09:38:40', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b0559127-0ccd-49f7-ae62-b85d3c105ff1'	System	15 Nov 2020 14:39:04
User entered 'No (N)'	System	15 Nov 2020 14:39:04

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-15T09:38:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b0559127-0ccd-49f7-ae62-b85d3c105ff1'	System	15 Nov 2020 14:39:04
User entered 'No (N)'	System	15 Nov 2020 14:39:04

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-15T09:38:59', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'b0559127-0ccd-49f7-ae62-b85d3c105ff1' User entered '15 Nov 2020 09:38:59'	System	15 Nov 2020 14:39:04
	System	15 Nov 2020 14:39:04

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 14:07:12

US3182145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:47
Data entry locked.	System	04 Aug 2020 14:07:12
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 14:07:12

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-22T12:43:01', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fca3e09c-abe2-4d53-9255-908bcc0d3b00'	System	22 Nov 2020 17:46:53
User entered 'No (N)'	System	22 Nov 2020 17:46:53

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-22T12:46:41', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fca3e09c-abe2-4d53-9255-908bcc0d3b00'	System	22 Nov 2020 17:46:53
User entered 'No (N)'	System	22 Nov 2020 17:46:53

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-22T12:46:49', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fca3e09c-abe2-4d53-9255-908bcc0d3b00' User entered '22 Nov 2020 12:46:49'	System	22 Nov 2020 17:46:53
	System	22 Nov 2020 17:46:53

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-26T07:14:36', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2b691304-3b16-4da7-b5d2-52c0d41e3fe7'	System	26 Nov 2020 12:14:48
User entered 'No (N)'	System	26 Nov 2020 12:14:48

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-26T07:14:41', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2b691304-3b16-4da7-b5d2-52c0d41e3fe7'	System	26 Nov 2020 12:14:48
User entered 'No (N)'	System	26 Nov 2020 12:14:48

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-11-26T07:14:45', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '2b691304-3b16-4da7-b5d2-52c0d41e3fe7' User entered '26 Nov 2020 07:14:45'	System	26 Nov 2020 12:14:48
	System	26 Nov 2020 12:14:48

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-03T00:01:46', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '419f4559-aed9-4fc6-b00f-f8fa1b967644'	System	03 Dec 2020 05:02:07
User entered 'No (N)'	System	03 Dec 2020 05:02:07

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-03T00:01:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '419f4559-aed9-4fc6-b00f-f8fa1b967644'	System	03 Dec 2020 05:02:07
User entered 'No (N)'	System	03 Dec 2020 05:02:07

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-03T00:01:55', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '419f4559-aed9-4fc6-b00f-f8fa1b967644' User entered '03 Dec 2020 00:01:55'	System	03 Dec 2020 05:02:07
	System	03 Dec 2020 05:02:07

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-11T07:46:42', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e8a10ed5-0da2-49bc-a9a6-4ca9aee58245'	System	11 Dec 2020 12:46:53
User entered 'No (N)'	System	11 Dec 2020 12:46:53

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-11T07:46:45', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e8a10ed5-0da2-49bc-a9a6-4ca9aee58245'	System	11 Dec 2020 12:46:53
User entered 'No (N)'	System	11 Dec 2020 12:46:53

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-11T07:46:51', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'e8a10ed5-0da2-49bc-a9a6-4ca9aee58245' User entered '11 Dec 2020 07:46:51'	System	11 Dec 2020 12:46:53
	System	11 Dec 2020 12:46:53

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-19T13:16:56', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1e970a44-983d-434b-98a9-745dfa49ff51'	System	19 Dec 2020 18:17:14
User entered 'No (N)'	System	19 Dec 2020 18:17:14

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-19T13:17:04', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1e970a44-983d-434b-98a9-745dfa49ff51'	System	19 Dec 2020 18:17:14
User entered 'No (N)'	System	19 Dec 2020 18:17:14

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-19T13:17:12', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1e970a44-983d-434b-98a9-745dfa49ff51'	System	19 Dec 2020 18:17:14
User entered '19 Dec 2020 13:17:12'	System	19 Dec 2020 18:17:14

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:33:14', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered 'Yes (Y)'	System	24 Dec 2020 05:35:39
	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:33:20', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered 'No (N)'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:33:43', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered 'Yes (Y)'	System	24 Dec 2020 05:35:39
	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39
	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '1'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '1'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '1'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39
	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '0'	System	24 Dec 2020 05:35:39
	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:39', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '1'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:34:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb'	System	24 Dec 2020 05:35:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:35:04', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered 'No (N)'	System	24 Dec 2020 05:35:39
	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2020-12-24T00:35:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '1c392a3e-8e4b-4ca8-82e3-830c2054a8bb' User entered '24 Dec 2020 00:35:28'	System	24 Dec 2020 05:35:39
	System	24 Dec 2020 05:35:39

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-01T17:17:23', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a8ebb90d-0d30-49b6-88a7-1a424734935f' User entered 'No (N)'	System	01 Jan 2021 22:17:50
	System	01 Jan 2021 22:17:50

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-01T17:17:26', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a8ebb90d-0d30-49b6-88a7-1a424734935f'	System	01 Jan 2021 22:17:50
User entered 'Yes (Y)'	System	01 Jan 2021 22:17:50

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-01T17:17:33', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a8ebb90d-0d30-49b6-88a7-1a424734935f'	System	01 Jan 2021 22:17:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 22:17:50

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-01T17:17:41', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'a8ebb90d-0d30-49b6-88a7-1a424734935f' User entered '01 Jan 2021 17:17:41'	System	01 Jan 2021 22:17:50
	System	01 Jan 2021 22:17:50

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-07T07:17:41', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '40033edb-37bb-44be-8a5e-6368eedb7dc9' User entered 'No (N)'	System	14 Jan 2021 11:32:29
	System	14 Jan 2021 11:32:29

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-07T07:17:47', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '40033edb-37bb-44be-8a5e-6368eedb7dc9'	System	14 Jan 2021 11:32:29
User entered 'No (N)'	System	14 Jan 2021 11:32:29

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-07T07:17:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '40033edb-37bb-44be-8a5e-6368eedb7dc9' User entered '07 Jan 2021 07:17:50'	System	14 Jan 2021 11:32:29

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-14T06:32:27', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fc1d290f-d533-4e9f-8bd3-f32edc146db0'	System	14 Jan 2021 11:32:41
User entered 'No (N)'	System	14 Jan 2021 11:32:41

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-14T06:32:35', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fc1d290f-d533-4e9f-8bd3-f32edc146db0'	System	14 Jan 2021 11:32:41
User entered 'No (N)'	System	14 Jan 2021 11:32:41

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-14T06:32:38', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'fc1d290f-d533-4e9f-8bd3-f32edc146db0'	System	14 Jan 2021 11:32:41
User entered '14 Jan 2021 06:32:38'	System	14 Jan 2021 11:32:41

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-21T00:13:34', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '63010f7a-497f-4690-8451-eba828dc2b20'	System	21 Jan 2021 05:13:48
User entered 'No (N)'	System	21 Jan 2021 05:13:48

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-21T00:13:37', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '63010f7a-497f-4690-8451-eba828dc2b20' User entered 'No (N)'	System	21 Jan 2021 05:13:48
	System	21 Jan 2021 05:13:48

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-21T00:13:44', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '63010f7a-497f-4690-8451-eba828dc2b20' User entered '21 Jan 2021 00:13:44'	System	21 Jan 2021 05:13:48
	System	21 Jan 2021 05:13:48

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-28T01:19:50', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '97f83538-a3fe-448c-b11c-c574b4cfe087'	System	28 Jan 2021 06:20:00
User entered 'No (N)'	System	28 Jan 2021 06:20:00

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-28T01:19:53', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '97f83538-a3fe-448c-b11c-c574b4cfe087'	System	28 Jan 2021 06:20:00
User entered 'No (N)'	System	28 Jan 2021 06:20:00

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-01-28T01:19:57', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '97f83538-a3fe-448c-b11c-c574b4cfe087'	System	28 Jan 2021 06:20:00
User entered '28 Jan 2021 01:19:57'	System	28 Jan 2021 06:20:00

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-04T00:24:06', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6e7f2717-ea3c-4236-b194-0447948dfcac'	System	04 Feb 2021 05:24:18
User entered 'No (N)'	System	04 Feb 2021 05:24:18

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-04T00:24:08', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6e7f2717-ea3c-4236-b194-0447948dfcac'	System	04 Feb 2021 05:24:18
User entered 'No (N)'	System	04 Feb 2021 05:24:18

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-04T00:24:14', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6e7f2717-ea3c-4236-b194-0447948dfcac'	System	04 Feb 2021 05:24:18
User entered '04 Feb 2021 00:24:14'	System	04 Feb 2021 05:24:18

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-11T00:02:25', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'f7232d98-3429-4032-94c3-0ccf2114fc3c'	System	11 Feb 2021 05:03:55
User entered 'No (N)'	System	11 Feb 2021 05:03:55

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-11T00:02:28', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'f7232d98-3429-4032-94c3-0ccf2114fc3c'	System	11 Feb 2021 05:03:55
User entered 'No (N)'	System	11 Feb 2021 05:03:55

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-11T00:02:31', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'f7232d98-3429-4032-94c3-0ccf2114fc3c' User entered '11 Feb 2021 00:02:31'	System	11 Feb 2021 05:03:55
	System	11 Feb 2021 05:03:55

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-18T00:08:09', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6c572b08-32cb-4526-9fda-746478233eb4' User entered 'No (N)'	System	18 Feb 2021 05:08:19
	System	18 Feb 2021 05:08:19

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-18T00:08:12', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6c572b08-32cb-4526-9fda-746478233eb4' User entered 'No (N)'	System	18 Feb 2021 05:08:19
	System	18 Feb 2021 05:08:19

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-18T00:08:16', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '6c572b08-32cb-4526-9fda-746478233eb4' User entered '18 Feb 2021 00:08:16'	System	18 Feb 2021 05:08:19
	System	18 Feb 2021 05:08:19

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-25T01:10:09-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '560fd0a6-725f-42a6-86f6-66d929c9d8e3'	System	25 Feb 2021 06:10:20
User entered 'No (N)'	System	25 Feb 2021 06:10:20

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-25T01:10:14-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '560fd0a6-725f-42a6-86f6-66d929c9d8e3'	System	25 Feb 2021 06:10:20
User entered 'No (N)'	System	25 Feb 2021 06:10:20

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-02-25T01:10:18-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '560fd0a6-725f-42a6-86f6-66d929c9d8e3'	System	25 Feb 2021 06:10:20
User entered '25 Feb 2021 06:10:18'	System	25 Feb 2021 06:10:20

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-04T00:09:32-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '35ba48c9-920e-43b6-b925-ed9fd01cff43'	System	04 Mar 2021 05:09:55
User entered 'No (N)'	System	04 Mar 2021 05:09:55

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-04T00:09:34-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '35ba48c9-920e-43b6-b925-ed9fd01cff43'	System	04 Mar 2021 05:09:55
User entered 'No (N)'	System	04 Mar 2021 05:09:55

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-04T00:09:37-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '35ba48c9-920e-43b6-b925-ed9fd01cff43'	System	04 Mar 2021 05:09:55
User entered '04 Mar 2021 00:09:37'	System	04 Mar 2021 05:09:55

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-11T02:52:46-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '3d9dcedf-886b-4705-b5e6-38423c1fc4e8'	System	11 Mar 2021 07:52:58
User entered 'No (N)'	System	11 Mar 2021 07:52:58

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-11T02:52:50-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '3d9dcedf-886b-4705-b5e6-38423c1fc4e8'	System	11 Mar 2021 07:52:58
User entered 'No (N)'	System	11 Mar 2021 07:52:58

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-11T02:52:53-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '3d9dcedf-886b-4705-b5e6-38423c1fc4e8' User entered '11 Mar 2021 02:52:53'	System	11 Mar 2021 07:52:58
	System	11 Mar 2021 07:52:58

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-18T00:13:09-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7db99716-fb75-4f5e-8cdd-9e6d70e377d2'	System	18 Mar 2021 04:13:18
User entered 'No (N)'	System	18 Mar 2021 04:13:18

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-18T00:13:11-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7db99716-fb75-4f5e-8cdd-9e6d70e377d2'	System	18 Mar 2021 04:13:18
User entered 'No (N)'	System	18 Mar 2021 04:13:18

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-18T00:13:15-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '7db99716-fb75-4f5e-8cdd-9e6d70e377d2'	System	18 Mar 2021 04:13:18
User entered '18 Mar 2021 00:13:15'	System	18 Mar 2021 04:13:18

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-25T00:32:25-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd7feff18-feb4-4950-a2e0-3edf4ef5bb17'	System	25 Mar 2021 04:32:33
User entered 'No (N)'	System	25 Mar 2021 04:32:33

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-25T00:32:28-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd7feff18-feb4-4950-a2e0-3edf4ef5bb17'	System	25 Mar 2021 04:32:33
User entered 'No (N)'	System	25 Mar 2021 04:32:33

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-25T00:32:31-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd7feff18-feb4-4950-a2e0-3edf4ef5bb17'	System	25 Mar 2021 04:32:33
User entered '25 Mar 2021 00:32:31'	System	25 Mar 2021 04:32:33

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-01T00:03:25-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd8d7c8bd-4609-4b64-b664-c411a61ce054'	System	01 Apr 2021 04:04:54
User entered 'No (N)'	System	01 Apr 2021 04:04:54

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-01T00:03:27-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd8d7c8bd-4609-4b64-b664-c411a61ce054'	System	01 Apr 2021 04:04:54
User entered 'No (N)'	System	01 Apr 2021 04:04:54

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-01T00:03:31-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'd8d7c8bd-4609-4b64-b664-c411a61ce054'	System	01 Apr 2021 04:04:54
User entered '01 Apr 2021 00:03:31'	System	01 Apr 2021 04:04:54

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-08T00:40:35-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '40212457-dd8e-43f1-9475-3fc23642b159' User entered 'No (N)'	System	08 Apr 2021 04:40:43
	System	08 Apr 2021 04:40:43

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-08T00:40:38-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '40212457-dd8e-43f1-9475-3fc23642b159'	System	08 Apr 2021 04:40:43
User entered 'No (N)'	System	08 Apr 2021 04:40:43

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-08T00:40:42-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '40212457-dd8e-43f1-9475-3fc23642b159'	System	08 Apr 2021 04:40:43
User entered '08 Apr 2021 00:40:42'	System	08 Apr 2021 04:40:43

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-15T00:19:11-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '03059c05-35d9-4da9-9b8a-23083b085a2f'	System	15 Apr 2021 04:19:23
User entered 'No (N)'	System	15 Apr 2021 04:19:23

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-15T00:19:15-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '03059c05-35d9-4da9-9b8a-23083b085a2f' User entered 'No (N)'	System	15 Apr 2021 04:19:23

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-15T00:19:18-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '03059c05-35d9-4da9-9b8a-23083b085a2f'	System	15 Apr 2021 04:19:23
User entered '15 Apr 2021 00:19:18'	System	15 Apr 2021 04:19:23

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-22T07:38:11-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'add5c75e-fd4f-453d-a4e4-7a19176e5472'	System	22 Apr 2021 11:38:20
User entered 'No (N)'	System	22 Apr 2021 11:38:20

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-22T07:38:15-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'add5c75e-fd4f-453d-a4e4-7a19176e5472'	System	22 Apr 2021 11:38:20
User entered 'No (N)'	System	22 Apr 2021 11:38:20

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-22T07:38:17-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'add5c75e-fd4f-453d-a4e4-7a19176e5472'	System	22 Apr 2021 11:38:20
User entered '22 Apr 2021 07:38:17'	System	22 Apr 2021 11:38:20

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-29T00:04:57-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '8f23cf08-91f4-4c79-b826-11df18c68afb' User entered 'No (N)'	System	29 Apr 2021 04:06:01

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

Have you been exposed to someone with 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 (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-29T00:04:59-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '8f23cf08-91f4-4c79-b826-11df18c68afb' User entered 'No (N)'	System	29 Apr 2021 04:06:01

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-04-29T00:05:03-04:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: '8f23cf08-91f4-4c79-b826-11df18c68afb' User entered '29 Apr 2021 00:05:03'	System	29 Apr 2021 04:06:01
	System	29 Apr 2021 04:06:01

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:20:30

US3182145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:20:30
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:20:30

US3182145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:32:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-04T00:09:48-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c1c98cfe-8f87-4647-ac3a-4b9869068cd0'	System	04 Mar 2021 05:10:02
User entered 'No (N)'	System	04 Mar 2021 05:10:02

US3182145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:32:13

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3FB156B0-7350-4CF0-ADCA-D6EF76A1426C)', Time: '2021-03-04T00:09:51-05:00', User OID: 'PatientReportedOutcome (US3182145)', ODM File OID: 'c1c98cfe-8f87-4647-ac3a-4b9869068cd0' User entered '04 Mar 2021 00:09:51'	System	04 Mar 2021 05:10:02
	System	04 Mar 2021 05:10:02

US3182145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski	13 Nov 2020 15:54:15

US3182145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '29 Oct 2020'	Cassie Uminski (b) (4)	13 Nov 2020 15:54:15

US3182145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	13 Nov 2020 15:54:15

US3182145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Nov 2020 15:54:15
	(b) (4)	

US3182145

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski	13 Nov 2020 15:54:56

US3182145

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:42:14
User entered 'I'	System	13 Nov 2020 15:54:56

US3182145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski	10 Dec 2020 02:49:17

US3182145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '01 Dec 2020'	Cassie Uminski (b) (4)	10 Dec 2020 02:49:17

US3182145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	10 Dec 2020 02:49:17

US3182145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	10 Dec 2020 02:49:17
	(b) (4)	

US3182145

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Dec 2020 02:49:08

US3182145

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User entered 'I'	System	10 Dec 2020 02:49:08

US3182145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:28:07

US3182145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '28 Dec 2020'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:28:07

US3182145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:28:07

US3182145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:28:07

US3182145

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:27:56

US3182145

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User entered 'I'	System	06 Jan 2021 14:27:56

US3182145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 14:12:02

US3182145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '27 Jan 2021'	Cassie Uminski (b) (4)	28 Jan 2021 14:12:02

US3182145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	28 Jan 2021 14:12:02

US3182145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	28 Jan 2021 14:12:02
	(b) (4)	

US3182145

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 14:12:10

US3182145

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User entered 'I'	System	28 Jan 2021 14:12:10

US3182145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:25:35

US3182145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:25:35

US3182145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	18 Feb 2021 16:25:35

US3182145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User entered 'VISIT4'	System	18 Feb 2021 16:25:35

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered '08:57'	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User entered '16 Feb 2021 08:57'	System	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered '98.2' F	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered empty.	(b) (4)	31 Mar 2021 14:13:40
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered '96'	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User entered 'bpm'	System	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered '16'	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User entered 'breaths/min'	System	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered '136'	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User entered 'mmHg'	System	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:52
User entered '89'	Cassie Uminski (b) (4)	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54
User entered 'mmHg'	System	31 Mar 2021 14:13:40

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54

US3182145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:54

US3182145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:25:43

US3182145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:25:43

US3182145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Mar 2021 18:04:54

US3182145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Mar 2021 18:04:54

US3182145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User entered '09:15'	Cassie Uminski (b) (4)	18 Mar 2021 18:04:54

US3182145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User entered '16 Feb 2021 09:15'	System	18 Mar 2021 18:04:54

US3182145

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:25:47

US3182145

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:27:47
User entered 'I'	System	18 Feb 2021 16:25:47

US3182145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:31
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:20
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 14:39:21

US3182145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:31
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:20
User entered '30 Mar 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 14:39:21

US3182145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:31
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 14:39:21

US3182145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:31
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:20
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	07 Apr 2021 14:39:21
	(b) (4)	

US3182145

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:31
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:20
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 14:39:37

US3182145

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:31
User entered 'I'	System	07 Apr 2021 14:39:37

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:13

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 12:56:14
User closed query 'Please check to see that all contacts with the subject are documented including rescheduled visits. ' (Site from CRA).	(b) (4)	19 Mar 2021 12:56:11
Query 'Please check to see that all contacts with the subject are documented including rescheduled visits. answered with 'Confirmed per Study coordinator' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	18 Mar 2021 18:01:46
User opened query 'Please check to see that all contacts with the subject are documented including rescheduled visits. ' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 12:49:16
User closed query 'When did they contact the site the first time to report the illness? ' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 12:49:16
Query 'When did they contact the site the first time to report the illness? ' answered with 'Per source, date and time subject called to report illness is 1/4/2021 at 12:00' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:31:19
User opened query 'When did they contact the site the first time to report the illness? ' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:13:50
User entered '04 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:49:24
User entered '04 Jan 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:47:46

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:13

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 12:56:16
User entered '12:00'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:47:46

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:13

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '04 Jan 2021 12:00'	System	05 Jan 2021 12:49:24
User entered '04 Jan 2020 12:00'	System	05 Jan 2021 12:47:46

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:13

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:13:53
User entered 'Safety Call (Safety Call)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:47:46

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:13

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:13:55
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:47:46

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 1 (Day 1)'	Cassie Uminski (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Toby Briskin (b) (4)	24 Apr 2021 17:37:34
Signature has been broken.	Naqib Ahmad (b) (4)	23 Apr 2021 20:05:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered '21 Dec 2020'	Cassie Uminski (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Toby Briskin (b) (4)	24 Apr 2021 17:37:34
Signature has been broken.	Naqib Ahmad (b) (4)	23 Apr 2021 20:05:27
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered '0'	Cassie Uminski (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:43
User signature succeeded.	Toby Briskin (b) (4)	24 Apr 2021 17:37:34
Signature has been broken.	Naqib Ahmad (b) (4)	23 Apr 2021 20:05:36
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:48
User signature succeeded.	Toby Briskin (b) (4)	24 Apr 2021 17:37:34
Signature has been broken.	Naqib Ahmad (b) (4)	23 Apr 2021 20:05:44
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Jan 2021 12:56:50

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 16:01:00
User signature succeeded.	Toby Briskin (b) (4)	24 Apr 2021 17:37:34
Signature has been broken.	Naqib Ahmad (b) (4)	23 Apr 2021 20:05:59
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4)	05 Jan 2021 12:56:50

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:53
User signature succeeded.	Toby Briskin (b) (4)	24 Apr 2021 17:37:34
Signature has been broken.	Naqib Ahmad (b) (4)	23 Apr 2021 20:05:52
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4)	05 Jan 2021 12:56:50

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:56:50

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 2 (Day 2)'	Cassie Uminski (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered '22 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User closed query 'Source has severe, CRF has moderate, please clarify. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:43
DataPoint Verified.		18 Feb 2021 17:43:40
Query 'Source has severe, CRF has moderate, please clarify. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	18 Feb 2021 16:31:36
DataPoint Un-verified.	(b) (4) Cassie Uminski (b) (4)	18 Feb 2021 16:31:31
User entered 'Severe (Severe)' reason for change:	(b) (4) Cassie Uminski (b) (4)	18 Feb 2021 16:31:31
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:23:11
User opened query 'Source has severe, CRF has moderate, please clarify. ' (Site from CRA).		21 Jan 2021 17:21:44
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:57:27

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 3 (Day 3)'	Cassie Uminski (b) (4)	05 Jan 2021 12:58:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered '23 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 12:58:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:15
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:58:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 4 (Day 4)'	Cassie Uminski (b) (4)	05 Jan 2021 12:59:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered '24 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 12:59:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:20
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:23

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 5 (Day 5)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered '25 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 12:59:49

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:24
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:59:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 6 (Day 6)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered '26 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 13:00:13

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:29
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:13

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 7 (Day 7)'	Cassie Uminski (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered '27 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:33
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:00:48

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 8 (Day 8)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered '28 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:38
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:16

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 9 (Day 9)'	Cassie Uminski (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered '29 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:42
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:01:56

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 10 (Day 10)'	Cassie Uminski (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered '30 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:23:47
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:02:26

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 11 (Day 11)'	Cassie Uminski (b) (4)	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered '31 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:12
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:14

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 12 (Day 12)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered '01 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered '0'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'Severe (Severe)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:25:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 13:03:43

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 19 (Day 19)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	13 Jan 2021 02:31:52
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	09 Jan 2021 02:34:35
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered '08 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered '0'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User closed query 'Please complete Covid-19 Severity Assessment ' (Site from CRA).		13 Jan 2021 14:28:21
Query 'Please complete Covid-19 Severity Assessment ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:32:49
User opened query 'Please complete Covid-19 Severity Assessment ' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 21:12:02
User entered '92'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered '97.4' F	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Jan 2021 02:34:35

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 20 (Day 20)'	Cassie Uminski (b) (4)	13 Jan 2021 02:31:52

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered '09 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered '98'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered '97.4' F	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:35:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:31:52

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 21 (Day 21)'	Cassie Uminski (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered '10 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered '98'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered '97.4' F	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:00

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 22 (Day 22)'	Cassie Uminski (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered '11 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered '96'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered '97.5' F	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:38:44

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 23 (Day 23)'	Cassie Uminski (b) (4)	13 Jan 2021 02:41:39

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered '12 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered '97'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered '%'	System	13 Jan 2021 02:41:39

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered '97.9' F	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:41:39

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 24 (Day 24)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User closed query 'Please provide source or remove data. ' (Site from CRA).		26 Apr 2021 19:20:12
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
Query 'Please provide source or remove data. ' answered with 'Source provided in chart ' (Site from CRA).	(b) (4) Jennifer Gaston (b) (4)	26 Apr 2021 16:02:22
DataPoint activated with code reason code Data required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4) Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User opened query 'Please provide source or remove data. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 12:44:17
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered '13 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	21 Jan 2021 01:44:24

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered '97'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint activated with code reason code Data required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
	(b) (4)	
User entered '%'	System	21 Jan 2021 01:44:24

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered '97.6' F	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:54
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:05
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:04
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:44:24
	(b) (4)	

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Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered 'Day 25 (Day 25)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User closed query 'Please provide source or remove data. ' (Site from CRA).		26 Apr 2021 19:20:24
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
Query 'Please provide source or remove data. ' answered with 'Source provided in chart' (Site from CRA).	(b) (4) Jennifer Gaston (b) (4)	26 Apr 2021 16:05:56
DataPoint activated with code reason code Data required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4) Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User opened query 'Please provide source or remove data. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 12:44:27
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
User entered '14 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	21 Jan 2021 01:45:19

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Generated On: 09 Jun 2021 15:32:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered '97'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint activated with code reason code Data required.	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
	(b) (4)	
User entered '%'	System	21 Jan 2021 01:45:19

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered '97.8' F	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 15:32:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		26 Apr 2021 19:20:59
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:02:11
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:00:38
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
	(b) (4)	
User entered 'None (None)'	Cassie Uminski (b) (4)	21 Jan 2021 01:45:19
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User closed query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4)	11 Mar 2021 09:05:49
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
Query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' answered with 'Please note that barcodes were scanned in and a requisition was received from the lab for the nasal swab' (Site from DM).	Cassie Uminski (b) (4)	10 Mar 2021 18:06:46
User opened query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:03:45
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:17:25
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4)	18 Jan 2021 12:36:57
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'COVID swab was collected 04-Jan-2021 Requisition # is 1F650964711' (Site from DM).	Cassie Uminski (b) (4)	13 Jan 2021 16:32:05

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:27
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	07 Jan 2021 17:35:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:29
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).		19 Jan 2021 17:20:31
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Updated' (Site from System).	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 16:32:15
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 Jan 2021 17:35:49
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	07 Jan 2021 17:35:49

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:33
User entered '04 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	07 Jan 2021 17:35:49

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:34
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassie Uminski (b) (4) (b) (4)	07 Jan 2021 17:35:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:36
User entered empty.	Cassie Uminski (b) (4) (b) (4)	07 Jan 2021 17:35:49

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:36
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	07 Jan 2021 17:35:49

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:36
User entered empty.	Cassie Uminski (b) (4) (b) (4)	07 Jan 2021 17:35:49

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:46:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:36
User entered empty.	Cassie Uminski (b) (4) (b) (4)	07 Jan 2021 17:35:49

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Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:13

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User entered 'I'	System	07 Jan 2021 17:35:49

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Generated On: 09 Jun 2021 15:32:13

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:24:22
User closed query 'Please clarify as values of \leq 93 are present in the symptom log. ' (Site from CRA).		15 Jan 2021 16:10:17
Query 'Please clarify as values of \leq 93 are present in the symptom log. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 13:33:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	14 Jan 2021 22:17:06
User opened query 'Please clarify as values of \leq 93 are present in the symptom log. ' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 14:27:51
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '05 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	05 Feb 2021 20:11:46
	(b) (4)	
User entered '08 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	05 Feb 2021 20:08:37
	(b) (4)	
User entered '05 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	14 Jan 2021 22:17:06
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '09 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Jan 2021 13:34:16
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

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Generated On: 09 Jun 2021 15:32:13

Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User closed query 'Please clarify as the symptom log has 92% on 08Jan2021. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:10:27
Query 'Please clarify as the symptom log has 92% on 08Jan2021. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	05 Feb 2021 20:08:41
User entered '92' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	05 Feb 2021 20:08:37
User opened query 'Please clarify as the symptom log has 92% on 08Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:23:58
User entered '98' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 13:34:16
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Generated On: 09 Jun 2021 15:32:13

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:53:48
Query 'Please complete. ' canceled (Site from CRA).		29 Mar 2021 12:53:02
DataPoint Un-verified.		29 Mar 2021 12:51:58
User opened query 'Please complete. ' (Site from CRA).		29 Mar 2021 12:51:47
Query 'Please complete. ' canceled (Site from CRA).		29 Mar 2021 12:51:30
DataPoint Verified.		29 Mar 2021 12:51:27
DataPoint Un-verified.		29 Mar 2021 12:51:19
User opened query 'Please complete. ' (Site from CRA).		29 Mar 2021 12:51:12
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:53:44
Query 'Please complete. ' canceled (Site from CRA).		29 Mar 2021 12:53:32
User opened query 'Please complete. ' (Site from CRA).		29 Mar 2021 12:52:17
DataPoint Un-verified.		29 Mar 2021 12:51:54
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:53:39
Query 'Please complete. ' canceled (Site from CRA).		29 Mar 2021 12:53:36
User opened query 'Please complete. ' (Site from CRA).		29 Mar 2021 12:52:39
DataPoint Un-verified.		29 Mar 2021 12:52:21
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Form: Covid-19 Severity Assessment

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:38:38
User closed query 'Please complete. ' (Site from CRA).		29 Mar 2021 18:36:41
Query 'Please complete. ' answered with 'updated.' (Site from CRA).	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:33
Signature has been broken.	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:28
User entered 'No (N)' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:28
User opened query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 12:54:04
DataPoint Un-verified.		29 Mar 2021 12:52:51
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:22:25
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:38:38
User closed query 'Please complete. ' (Site from CRA).		29 Mar 2021 18:36:54
Query 'Please complete. ' answered with 'updated.' (Site from CRA).	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:35
Signature has been broken.	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:28
User entered 'No (N)' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:28
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 12:54:29
User opened query 'Please complete. ' (Site from CRA).		29 Mar 2021 12:54:27
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:22:25
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:38:38
User closed query 'Please complete. ' (Site from CRA).		29 Mar 2021 18:37:06
Query 'Please complete. ' answered with 'updated.' (Site from CRA).	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:39
Signature has been broken.	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:28
User entered 'No (N)' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:28
User opened query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 12:55:02
DataPoint Un-verified.		29 Mar 2021 12:54:34
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:38:38
User closed query 'Please complete. ' (Site from CRA).		29 Mar 2021 18:37:23
Query 'Please complete. ' answered with 'updated.' (Site from CRA).	Naqib Ahmad (b) (4)	29 Mar 2021 13:20:41
Signature has been broken.	(b) (4) Naqib Ahmad (b) (4)	29 Mar 2021 13:20:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	29 Mar 2021 13:20:28
User opened query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 12:55:32
DataPoint Un-verified.		29 Mar 2021 12:54:39
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:37:55
User closed query 'Please complete. ' (Site from CRA).		29 Mar 2021 18:37:37
Query 'Please complete. ' answered with 'updated.' (Site from CRA).	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:44
Signature has been broken.	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:28
User entered 'No (N)' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	29 Mar 2021 13:20:28
User opened query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 12:55:49
DataPoint Un-verified.		29 Mar 2021 12:55:37
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 02:35:36

US3182145

Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:32:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
DataPoint Verified.		29 Mar 2021 12:50:28
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 02:35:36
	(b) (4)	

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Folder: Covid-19 Assessment 04 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:32:13

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:46
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:48:43

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:32:21
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 07JAN2021 is reported for Day 3 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:00:51
User closed query 'Source has 06Jan2021, CRF has 07Jan2021, Lab has 07Jan2021. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:32:24
DataPoint Verified.		20 Apr 2021 19:32:23
Query 'Per GCL Lab Recon: Saliva: Sample dated 07JAN2021 is reported for Day 3 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' answered with 'Confirmed as 06Jan2021, DCF to be created for PPD' (Site from DM).	Jennifer Gaston (b) (4)	20 Apr 2021 15:03:10
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 07JAN2021 is reported for Day 3 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:31:56
User signature succeeded.	Mary Beth Manning (b) (4)	14 Apr 2021 15:42:54
Query 'Source has 06Jan2021, CRF has 07Jan2021, Lab has 07Jan2021. Please clarify. ' answered with '06Jan is correct DCF to be done' (Site from CRA).	Jennifer Gaston (b) (4)	08 Apr 2021 20:17:21
Signature has been broken.	Jennifer Gaston (b) (4)	08 Apr 2021 16:40:22
User entered '06 Jan 2021' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	08 Apr 2021 16:40:22

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Source has 06Jan2021, CRF has 07Jan2021, Lab has 07Jan2021. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:12:47
User closed query 'Please provide saliva source including when the subject collected the sample. ' (Site from CRA).		31 Mar 2021 14:26:36
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
Query 'Please provide saliva source including when the subject collected the sample. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	18 Mar 2021 18:02:26
	(b) (4)	
User opened query 'Please provide saliva source including when the subject collected the sample. ' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 12:45:39
User closed query 'Please confirm date of collection as day 3 was 06Jan2021. ' (Site from CRA).		20 Feb 2021 12:45:39
User closed query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 07JAN2021 is reported in PPD central lab with 07JAN2020 date. Please review Preclarus to confirm the Year 2020 reported and update Preclarus, as applicable. Also confirm the correct date in the response. Thank you.' (Site from DM).		19 Jan 2021 15:33:42
Query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 07JAN2021 is reported in PPD central lab with 07JAN2020 date. Please review Preclarus to confirm the Year 2020 reported and update Preclarus, as applicable. Also confirm the correct date in the response. Thank you.' answered with 'Confirmed year should be 2021, a DCF will be submitted to PPD' (Site from DM).	Cassie Uminski (b) (4)	15 Jan 2021 13:39:33
	(b) (4)	
User entered '07 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Jan 2021 13:36:40
	(b) (4)	
Query 'Please confirm date of collection as day 3 was 06Jan2021. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	15 Jan 2021 13:36:21
	(b) (4)	
User entered '06 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Jan 2021 13:36:11
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 07JAN2021 is reported in PPD central lab with 07JAN2020 date. Please review Preclarus to confirm the Year 2020 reported and update Preclarus, as applicable. Also confirm the correct date in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 06:31:25
User opened query 'Please confirm date of collection as day 3 was 06Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 18:12:03
User entered '07 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Source and lab have 08Jan2021, CRF has not done. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	18 Apr 2021 15:56:57
DataPoint Verified.		18 Apr 2021 15:56:53
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:54
Query 'Source and lab have 08Jan2021, CRF has not done. Please clarify. ' answered with 'updated.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:02:37
Signature has been broken.		13 Apr 2021 21:02:28
User entered 'Yes (Y)' reason for change: Data Entry Error		13 Apr 2021 21:02:28
User opened query 'Source and lab have 08Jan2021, CRF has not done. Please clarify. ' (Site from CRA).		02 Apr 2021 15:13:44
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User closed query 'Per ETRTR, Please confirm response and update if needed. According to PPD labs, Saliva sample was not collected for Day 5. Please reconcile and ensure PD is recorded if applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:58:54
Query 'Per ETRTR, Please confirm response and update if needed. According to PPD labs, Saliva sample was not collected for Day 5. Please reconcile and ensure PD is recorded if applicable.' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:35:43
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:35:33
User opened query 'Per ETRTR, Please confirm response and update if needed. According to PPD labs, Saliva sample was not collected for Day 5. Please reconcile and ensure PD is recorded if applicable.' (Site from CRA).	(b) (4), (b) (6)	31 Jan 2021 23:39:24
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 13:36:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 13:36:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 13:36:11

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EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:11:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 15:56:54
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:54
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 21:02:28
User entered '08 Jan 2021' reason for change: Data Entry Error		13 Apr 2021 21:02:28
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4)	18 Feb 2021 16:35:33
	(b) (4)	
User entered '08 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Jan 2021 13:36:11
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:13

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F650573392 is reported with 11JAN2021 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:57:09
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F650573392 is reported with 11JAN2021 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4)	18 Feb 2021 16:38:39
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F650573392 is reported with 11JAN2021 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 16:29:22
User accepted default value 'Day 7 (Day 7)'	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:32:52
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 13:36:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 13:36:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Jan 2021 13:36:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:11:41
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Source and CRF have 10Jan2021, Lab has 11Jan2021. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:32:57
DataPoint Verified.		20 Apr 2021 19:32:54
Query 'Source and CRF have 10Jan2021, Lab has 11Jan2021. Please clarify. ' answered with '10Jan2021 correct as is, DCF to be created for PPD' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	20 Apr 2021 15:03:51
User opened query 'Source and CRF have 10Jan2021, Lab has 11Jan2021. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	18 Apr 2021 15:58:03
User closed query 'Source has 10Jan2021 Lab and CRF have 11Jan2021. Please clarify. ' (Site from CRA).		18 Apr 2021 15:58:03
User signature succeeded.	Mary Beth Manning (b) (4)	14 Apr 2021 15:42:54
Query 'Source has 10Jan2021 Lab and CRF have 11Jan2021. Please clarify. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:03:34
Signature has been broken.		13 Apr 2021 21:03:26
User entered '10 Jan 2021' reason for change: Data Entry Error		13 Apr 2021 21:03:26
User opened query 'Source has 10Jan2021 Lab and CRF have 11Jan2021. Please clarify. ' (Site from CRA).		02 Apr 2021 15:14:51
User signature succeeded.	Mary Beth Manning (b) (4)	20 Mar 2021 20:42:41
User entered '11 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:38:36
User entered '10 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 13:36:11
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:15:07
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 13:36:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 13:36:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Jan 2021 13:36:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:11:41
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:15:08
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User entered '12 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Jan 2021 13:36:11
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:15:27
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User closed query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 20:24:56
Query 'Please complete. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	09 Mar 2021 16:46:51
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Mar 2021 16:46:44
	(b) (4)	
User opened query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:51:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Jan 2021 03:37:17
Query 'Data is required. Please complete.' answered with 'This day has not yet occurred. Data will be updated once available.' (Site from System).	Cassie Uminski (b) (4)	15 Jan 2021 13:40:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:11:41
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:15:29
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User entered '17 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Mar 2021 16:46:44
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:13

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F638480018 is reported with 24JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 10:00:19
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F638480018 is reported with 24JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' answered with 'Corrected.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 21:05:07
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F638480018 is reported with 24JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:41:07
User accepted default value 'Day 21 (Day 21)'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 15:56:26
User closed query 'Source and lab have 24Jan2021 CRF has not done. Please clarify. ' (Site from CRA).	(b) (4)	18 Apr 2021 15:56:24
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:54
Query 'Source and lab have 24Jan2021 CRF has not done. Please clarify. ' answered with 'Corrected.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:05:13
Signature has been broken.	(b) (4)	13 Apr 2021 21:04:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	13 Apr 2021 21:04:09
User opened query 'Source and lab have 24Jan2021 CRF has not done. Please clarify. ' (Site from CRA).	(b) (4)	02 Apr 2021 15:16:15
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User closed query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 20:25:02
Query 'Please complete. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	09 Mar 2021 16:46:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 16:46:04
User opened query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:51:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Jan 2021 03:37:21
Query 'Data is required. Please complete.' answered with 'This day has not yet occurred. Data will be updated once available.' (Site from System).	Cassie Uminski (b) (4)	15 Jan 2021 13:40:59
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:11:41
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 15:56:28
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:54
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 21:04:09
User entered '24 Jan 2021' reason for change: Data Entry Error		13 Apr 2021 21:04:09
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:01:45
User closed query 'Please complete. ' (Site from CRA).		19 Feb 2021 13:59:24
Query 'Please complete. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:40:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:39:59
User opened query 'Please complete. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:51:44
User closed query 'Data is required. Please complete.' (Site from System).		18 Jan 2021 03:37:26
Query 'Data is required. Please complete.' answered with 'This day has not yet occurred. Data will be updated once available.' (Site from System).	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 13:41:07
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:11:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:11:41

US3182145

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 13:01:45
User entered '01 Feb 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	18 Feb 2021 16:39:59
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 18:11:41
	(b) (4)	

US3182145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:56
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:49:07

US3182145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:56
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	05 Jan 2021 12:49:14
User entered '04 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:49:14
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	05 Jan 2021 12:49:07
User entered '04 Jan 2020'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:49:07

US3182145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:17:56
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:49:07

US3182145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User entered 'SICKD1'	System	05 Jan 2021 12:49:07

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered '04 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered '12:10'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User entered '04 Jan 2021 12:10'	System	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered '158.4' cm	Cassie Uminski (b) (4)	05 Jan 2021 12:52:36
DataPoint set to visible.	(b) (4) System	05 Jan 2021 12:49:07

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered '83.91' kg	Cassie Uminski (b) (4)	05 Jan 2021 12:52:36
DataPoint set to visible.	(b) (4) System	05 Jan 2021 12:49:07

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered '98.8' F	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered empty.	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered '94'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User entered 'bpm'	System	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered '15'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User entered 'breaths/min'	System	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User entered '131'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User entered 'mmHg'	System	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:04
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		18 Jan 2021 03:36:42
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 13:35:15
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Jan 2021 12:52:36
User entered '105'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User entered 'mmHg'	System	05 Jan 2021 12:52:36

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41

US3182145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41

US3182145

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:21
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:53:52

US3182145

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:21
User entered '04 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:53:52

US3182145

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:32:13

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:54:35

US3182145

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:19:33
User entered '04 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	05 Jan 2021 12:54:35

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 12:59:10
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:07:58

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 12:59:10
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '01 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:07:58

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 12:59:10
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Clinic (Clinic)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:07:58

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
User entered 'SICKD28'	System	02 Feb 2021 15:07:58

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '01 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '09:20'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
User entered '01 Feb 2021 09:20'	System	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	02 Feb 2021 15:08:30
DataPoint set to visible.	(b) (4) System	02 Feb 2021 15:07:58

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	02 Feb 2021 15:08:30
DataPoint set to visible.	(b) (4) System	02 Feb 2021 15:07:58

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '97.3' F	(b) (4)	
	Cassie Uminski (b) (4)	02 Feb 2021 15:08:30
	(b) (4)	

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Feb 2021 15:08:30
	(b) (4)	

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '82'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
User entered 'bpm'	System	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
User entered 'breaths/min'	System	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '162'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
User entered 'mmHg'	System	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:00:58
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
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)	11 Feb 2021 17:59:17
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		11 Feb 2021 17:59:15
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 'Subject did not take medications prior to appointment' (Site from System).	Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:09:41
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject did not take medications prior to appointment' (Site from System).	Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:09:37
User opened query 'Diastolic Blood Pressure reported System 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).		02 Feb 2021 15:08:30
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Feb 2021 15:08:30
User entered '112'	Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
User entered 'mmHg'	System	02 Feb 2021 15:08:30

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:01:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:10:00

US3182145

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:01:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '01 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:10:00

US3182145

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:32:13

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:01:37
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:10:13

US3182145

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:32:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:37
DataPoint Verified.		19 Mar 2021 13:01:37
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '01 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Feb 2021 15:10:13

US3182145

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:26

US3182145

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:26

US3182145

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:26

US3182145

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'UNBLND_DECIDE'	System	18 Feb 2021 16:26:26

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:27:16

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[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 19:35:14
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:14:54

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:27:16

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
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 16:14:54

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:27:16

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4)	18 Feb 2021 16:27:16

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4)	18 Feb 2021 16:27:16

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4)	18 Feb 2021 16:27:16

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:27:16

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '1'	System	18 Feb 2021 16:27:16

US3182145

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'I'	System	18 Feb 2021 16:27:16

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '167.8' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '83.9' kg	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '29.79738'	System	18 Feb 2021 16:28:18
DataPoint set to visible.	System	18 Feb 2021 16:27:16

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '167.8' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '83.9' kg	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '29.79738'	System	18 Feb 2021 16:28:18
DataPoint set to visible.	System	18 Feb 2021 16:27:16

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '08:57'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '16 Feb 2021 08:57'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '98.2' F	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	18 Feb 2021 16:28:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '96'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'bpm'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'breaths/min'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '136'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mmHg'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '89'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mmHg'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '167.8' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '83.9' kg	(b) (4) Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '29.79738'	System	18 Feb 2021 16:28:18
DataPoint set to visible.	System	18 Feb 2021 16:27:16

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '10:00'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '16 Feb 2021 10:00'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '98.3' F	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '87'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'bpm'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'breaths/min'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '128'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mmHg'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '89'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:18

US3182145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mmHg'	System	18 Feb 2021 16:28:18

US3182145

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:41

US3182145

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:28:41

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:29:02

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	18 Feb 2021 16:29:02
	Cassie Uminski (b) (4)	
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

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 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	Cassie Uminski (b) (4)	18 Feb 2021 16:29:02

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mRNA-1273'	System	18 Feb 2021 16:29:02
DataPoint set to visible.	System	18 Feb 2021 16:27:16

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:29:02

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '09:30'	Cassie Uminski (b) (4)	18 Feb 2021 16:29:02

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '16 Feb 2021 09:30'	System	18 Feb 2021 16:29:02

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Left Arm (LEFT ARM)'	Cassie Uminski (b) (4)	18 Feb 2021 16:29:02

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'ONCE'	System	18 Feb 2021 16:29:02

US3182145

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

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'INTRAMUSCULAR'	System	18 Feb 2021 16:29:02

US3182145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:53

US3182145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:53

US3182145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '09:15'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:53

US3182145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '16 Feb 2021 09:15'	System	18 Feb 2021 16:26:53

US3182145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:36

US3182145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:36

US3182145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:13

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '09:10'	Cassie Uminski (b) (4)	18 Feb 2021 16:26:36

US3182145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:13

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '16 Feb 2021 09:10'	System	18 Feb 2021 16:26:36

US3182145

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

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Feb 2021 16:27:26

US3182145

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

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '1'	System	18 Feb 2021 16:27:26

US3182145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	16 Mar 2021 15:52:05

US3182145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '24 Feb 2021'	Cassie Uminski (b) (4)	16 Mar 2021 15:52:05

US3182145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	16 Mar 2021 15:52:05

US3182145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered empty.	(b) (4)	16 Mar 2021 15:52:05
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	16 Mar 2021 15:37:50

US3182145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'I'	System	16 Mar 2021 15:37:50

US3182145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'I'	System	16 Mar 2021 15:37:50
DataPoint set to visible.	System	16 Mar 2021 15:37:50

US3182145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	16 Mar 2021 15:38:12

US3182145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '16 Mar 2021'	Cassie Uminski (b) (4)	16 Mar 2021 15:38:12

US3182145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[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 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	16 Mar 2021 15:38:12

US3182145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'OLD29'	System	16 Mar 2021 15:38:12

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '16 Mar 2021'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '08:28'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '16 Mar 2021 08:28'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '98.2' F	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered empty.	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '76'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'bpm'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '16'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'breaths/min'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '144'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mmHg'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '99'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mmHg'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '16 Mar 2021'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '09:20'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '16 Mar 2021 09:20'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '98.6' F	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered empty.	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '66'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'bpm'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '16'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'breaths/min'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '145'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mmHg'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '99'	Cassie Uminski (b) (4)	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mmHg'	System	16 Mar 2021 15:40:54

US3182145

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	16 Mar 2021 15:41:34

US3182145

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered '16 Mar 2021'	Cassie Uminski (b) (4)	16 Mar 2021 15:41:34

US3182145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	16 Mar 2021 15:41:52

US3182145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User entered empty.	Cassie Uminski (b) (4)	16 Mar 2021 15:41:52

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

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 19:35:14
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User entered empty.	Cassie Uminski (b) (4)	16 Mar 2021 15:41:52

US3182145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'mRNA-1273'	System	16 Mar 2021 15:41:52
DataPoint set to visible.	System	16 Mar 2021 15:37:50

US3182145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User entered '16 Mar 2021'	Cassie Uminski (b) (4)	16 Mar 2021 15:41:52

US3182145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
User entered '08:50'	Cassie Uminski (b) (4)	16 Mar 2021 15:41:52

US3182145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered '16 Mar 2021 08:50'	System	16 Mar 2021 15:41:52

US3182145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).		22 Mar 2021 13:15:48
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'This was completed in right arm per subject request' (Site from System).	Cassie Uminski (b) (4)	18 Mar 2021 18:02:58
	(b) (4)	
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	16 Mar 2021 15:41:52
User entered 'Right Arm (RIGHT ARM)'	Cassie Uminski (b) (4)	16 Mar 2021 15:41:52
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'ONCE'	System	16 Mar 2021 15:41:52

US3182145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'INTRAMUSCULAR'	System	16 Mar 2021 15:41:52

US3182145

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:01:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	16 Mar 2021 15:45:38

US3182145

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'I'	System	16 Mar 2021 15:45:38

US3182145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Mar 2021 17:27:22

US3182145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
User entered '23 Mar 2021'	Cassie Uminski (b) (4)	29 Mar 2021 17:27:22

US3182145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	29 Mar 2021 17:27:22

US3182145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Mar 2021 17:27:22
	(b) (4)	

US3182145

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:52:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Mar 2021 17:27:27

US3182145

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:35:14
User entered 'I'	System	29 Mar 2021 17:27:27

US3182145

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:15:08

US3182145

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:27
	(b) (4)	
User entered '14 Apr 2021'	Cassie Uminski (b) (4)	14 Apr 2021 17:15:08
	(b) (4)	

US3182145

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:15:08

US3182145

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:13

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	14 Apr 2021 17:15:08

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:27
	(b) (4)	
User entered '14 Apr 2021'	Cassie Uminski (b) (4)	14 Apr 2021 17:16:56
	(b) (4)	

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:27
	(b) (4)	
User entered '08:45'	Cassie Uminski (b) (4)	14 Apr 2021 17:16:56
	(b) (4)	

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Apr 2021 08:45'	System	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered '97.9' F	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:27
	(b) (4)	
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	14 Apr 2021 17:16:56
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered empty.	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered '65'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered '16'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered '165'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 14:34:55
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:27
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Cassie Uminski (b) (4)	14 Apr 2021 17:17:03
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		14 Apr 2021 17:16:56
User entered '105'	Cassie Uminski (b) (4)	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Apr 2021 17:16:56

US3182145

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:17:15

US3182145

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:27
	(b) (4)	
User entered '14 Apr 2021'	Cassie Uminski (b) (4)	14 Apr 2021 17:17:15
	(b) (4)	

US3182145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:17:24

US3182145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:27
	(b) (4)	
User entered '14 Apr 2021'	Cassie Uminski (b) (4)	14 Apr 2021 17:17:24
	(b) (4)	

US3182145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	14 Apr 2021 19:52:27
User entered '09:25'	Cassie Uminski (b) (4) (b) (4)	14 Apr 2021 17:17:24

US3182145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Apr 2021 09:25'	System	14 Apr 2021 17:17:24

US3182145

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:32:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:31:13
DataPoint Verified.		20 Apr 2021 19:29:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 16:39:17

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:34
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered	System	13 Jan 2021 23:22:36
'USA-US075-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	13 Jan 2021 23:22:36

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:35
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User closed query 'Per completion guidelines this is to be Covid-19 or symptomatic Covid-19, Please update. ' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 16:07:11
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)	14 Jan 2021 22:09:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 22:09:58
	(b) (4)	
Data point term sent to Coder	System	14 Jan 2021 22:08:55
Query 'Per completion guidelines this is to be Covid-19 or symptomatic Covid-19, Please update. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	14 Jan 2021 22:08:53
	(b) (4)	
Coding entries removed.	Cassie Uminski (b) (4)	14 Jan 2021 22:08:36
	(b) (4)	
User entered 'COVID-19' reason for change: Data Entry Error	Cassie Uminski (b) (4)	14 Jan 2021 22:08:36
	(b) (4)	
User opened query 'Per completion guidelines this is to be Covid-19 or symptomatic Covid-19, Please update. ' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 17:30:38
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)	13 Jan 2021 16:42:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 16:42:01
	(b) (4)	
Data point term sent to Coder	System	13 Jan 2021 16:41:37
User entered 'Positive COVID'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:37
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:51
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:58
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Jan 2021 16:41:41
User entered '21 Dec 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	13 Jan 2021 16:41:41
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Jan 2021 16:41:02
User entered '21 Dec 2021'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:00
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 16:41:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:02
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 13:41:43
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	18 Mar 2021 13:41:43
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 13:41:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	02 Feb 2021 15:01:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:07
User closed query 'Please complete end date once confirmed with an investigator. ' (Site from CRA).	(b) (4)	19 Mar 2021 16:43:59
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
Query 'Please complete end date once confirmed with an investigator. ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4)	18 Mar 2021 13:41:49
	(b) (4)	
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	18 Mar 2021 13:41:43
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	18 Mar 2021 13:41:43
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	18 Mar 2021 13:41:15
User entered '08 Jan 2021' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	18 Mar 2021 13:41:15
	(b) (4)	
User opened query 'Please complete end date once confirmed with an investigator. ' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 12:43:22
User closed query 'Please confirm end date with investigator due to O2 levels. ' (Site from CRA).	(b) (4)	20 Feb 2021 12:43:22
Query 'Please confirm end date with investigator due to O2 levels. ' answered with 'Information will be updated' (Site from CRA).	Cassie Uminski (b) (4)	02 Feb 2021 15:04:43
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4)	02 Feb 2021 15:01:55
	(b) (4)	
User opened query 'Please confirm end date with investigator due to O2 levels. ' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:31:19
User closed query 'Please clarify as the symptom log has the O2 sat at 92% on 08Jan2021. ' (Site from CRA).	(b) (4)	21 Jan 2021 17:31:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Please clarify as the symptom log has the O2 sat at 92% on 08Jan2021. ' answered with 'Correct as is' (Site from CRA).	Cassie Uminski (b) (4)	14 Jan 2021 22:11:42
User opened query 'Please clarify as the symptom log has the O2 sat at 92% on 08Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 17:33:10
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	13 Jan 2021 16:41:41
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	13 Jan 2021 16:41:02
User entered '05 Jan 2021'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:12
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 16:41:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:15
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:19
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:29
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:31
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:33
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:35
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:38
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:39
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:42
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:43
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:46
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:50
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:56
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:58
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:21:59
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User closed query 'PV Query: As the last dose of study drug was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 20:57:39
Query 'PV Query: As the last dose of study drug was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.'	Cassie Uminski (b) (4)	02 Feb 2021 15:04:53
answered with 'Updated' (Site from Safety).	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4)	02 Feb 2021 15:01:55
reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 13:12:37
User entered 'None (NONE)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:22:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:22:07
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
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)	10 Feb 2021 20:57:43
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 'Con med is on con med log' (Site from Safety).	Cassie Uminski (b) (4)	02 Feb 2021 15:05:47
	(b) (4)	
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)	25 Jan 2021 13:11:41
User entered 'I'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:22:12
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:22:13
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	18 Mar 2021 13:41:43
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	02 Feb 2021 15:01:55
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:22:15
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:22:17
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:35:08
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	13 Jan 2021 16:41:02
	(b) (4)	

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Jan 2021 16:41:02

US3182145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Jan 2021 16:41:02

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:32:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:31:13
DataPoint Verified.		12 Apr 2021 15:37:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:40:06

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Aug 2020 14:42:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:42:09
Data point term sent to Coder	System	07 Aug 2020 14:41:09
User entered 'Lisinopril'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:40:43

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Hypertension'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '20'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:25:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 14:40:43
User entered 'un UNK 2017'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:40:43

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:40:43
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:40:43

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:40:43

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 14:40:43

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Aug 2020 14:43:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:43:18
Data point term sent to Coder	System	07 Aug 2020 14:42:11
User entered 'Allegra'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:41:24

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '180' reason for change: Data Entry	Cassie Uminski (b) (4)	09 Oct 2020 13:00:52
Error	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Oct 2020 12:06:35
Query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	09 Oct 2020 13:01:02
User entered 'mg (mg)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	09 Oct 2020 13:00:52
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 04:26:50
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:41:24

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User closed query 'Please clarify start date. I don't think it was available until 1996. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:13:29
Comment added 'Updated, valacyclovir entered in error'.	Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:01:14
Query 'Please clarify start date. I don't think it was available until 1996. ' answered with 'valacyclovir' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:00:59
User entered 'UN UNK 1999' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:00:46
User opened query 'Please clarify start date. I don't think it was available until 1996. ' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 18:56:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		12 Aug 2020 14:25:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 14:41:24
User entered 'un UNK 1980'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:41:24

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:24
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:41:24

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:41:24

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:41:24

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 13:03:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:03:22
Data point term sent to Coder Coding entries removed.	System Cassie Uminski (b) (4) (b) (4)	09 Oct 2020 13:02:24 09 Oct 2020 13:01:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:56:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:56:16
Data point term sent to Coder User entered 'Ibuprofen'	System Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:42:11 07 Aug 2020 14:41:45

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'left knee OSTEOARTHRITIS PAIN'	Cassie Uminski (b) (4)	09 Oct 2020 13:01:51
reason for change: Data Entry Error	(b) (4)	
Query 'Per DM CLR: Please update the indication to specify the location of OSTEOARTHRITIS PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:07:19
User opened query 'Per DM CLR: Please update the indication to specify the location of OSTEOARTHRITIS PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:17:40
User entered 'Osteoarthritis Pain'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '200' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Oct 2020 13:01:23
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Oct 2020 12:06:48
Query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	09 Oct 2020 13:01:27
User entered 'mg (mg)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	09 Oct 2020 13:01:23
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:17:52
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:41:45

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:25:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 14:41:45
User entered 'un UNK 2019'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:41:45

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 14:41:45
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:41:45

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:41:45

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:41:45

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 18:14:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:14:50
Data point term sent to Coder	System	02 Oct 2020 18:13:38
User entered 'Hydrochlorothiazide'	Cassie Uminski (b) (4) (b) (4)	02 Oct 2020 18:13:10

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User closed query 'Per DM CLR: Con Med HYDROCHLOROTHIAZIDE was added on 07 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: Con Med HYDROCHLOROTHIAZIDE was added on 07 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'Condition is consistent, investigator determined NCS and no AE noted.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 02:10:20
User opened query 'Per DM CLR: Con Med HYDROCHLOROTHIAZIDE was added on 07 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'Condition is consistent, investigator determined NCS and no AE noted.' (Site from DM).	Brooke Glivar (b) (4) (b) (4)	24 Nov 2020 15:24:53
User entered 'Hypertension'	(b) (4), (b) (6)	05 Nov 2020 14:18:26
	Cassie Uminski (b) (4) (b) (4)	02 Oct 2020 18:13:10

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '25'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

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

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '07 Aug 2020'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Oct 2020 18:13:10
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:13:10

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:13:10

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:13:10

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 19:03:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 19:03:24
Data point term sent to Coder	System	19 Oct 2020 19:02:46
User entered 'Acetaminophen'	Cassie Uminski (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4)	19 Oct 2020 19:02:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 02:10:45
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'This does not meet AE criteria' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 15:27:13
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:19:02
User entered 'Headache'	Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '500'	(b) (4) Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	19 Oct 2020 19:02:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	19 Oct 2020 19:02:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4)	19 Oct 2020 19:02:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '05 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '05 Aug 2020'	Cassie Uminski (b) (4)	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	24 Nov 2020 15:26:50
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	19 Oct 2020 19:02:18
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User entered '1'	System	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User entered '1'	System	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:19
User entered '804 (804)'	System	19 Oct 2020 19:02:18

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.	(b) (4)	19 Mar 2021 13:05:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Jan 2021 23:23:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:23:59
Data point term sent to Coder	System	14 Jan 2021 22:10:15
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	14 Jan 2021 22:09:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:20:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:20:53
Data point term sent to Coder	System	08 Jan 2021 14:19:53
User entered 'Ibuprofen'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:05:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:05:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'HEADACHE (secondary to COVID-19)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	14 Jan 2021 22:09:33
	(b) (4)	
User entered 'Headache'	Cassie Uminski (b) (4)	08 Jan 2021 14:19:50
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User closed query 'Please clarify as source states 2 200 mg tablets. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:49:19
DataPoint Verified.		04 Feb 2021 16:49:12
Query 'Please clarify as source states 2 200 mg tablets. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	02 Feb 2021 15:05:31
User entered '400' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	02 Feb 2021 15:05:26
User opened query 'Please clarify as source states 2 200 mg tablets. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:58:02
User entered '200'	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:05:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:05:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	08 Jan 2021 14:19:50
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Jan 2021 14:19:50
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'Oral (ORAL)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '22 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
User entered '30 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
DataPoint Verified.		19 Mar 2021 13:06:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	13 Jan 2021 16:41:57
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	08 Jan 2021 14:19:50
	(b) (4)	

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
User entered '1'	System	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
User entered '1'	System	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:38:20
User entered '804 (804)'	System	08 Jan 2021 14:19:50

US3182145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:32:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:29:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Feb 2021 02:00:42
	(b) (4)	

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered	System	13 Jan 2021 23:22:36
'USA-US075-2021-MRNA-1273-P301000001'		

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:59
DataPoint Verified.		02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'Jennifer'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
Signature has been broken.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
User entered 'Briskin' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:01
DataPoint Verified.		02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'Gaston'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'OH'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'US'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Mar 2021 19:43:13
User entered '2'	System	11 Feb 2021 21:36:50
User entered '1'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered	System	13 Jan 2021 23:22:36
'USA-US075-2021-MRNA-1273-P301000001'		

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:59
DataPoint Verified.		02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'Jennifer'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
Signature has been broken.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
User entered 'Briskin' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:01
DataPoint Verified.		02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'Gaston'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'OH'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'US'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Mar 2021 19:43:13
User entered '2'	System	11 Feb 2021 21:36:50
User entered '1'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '13/Jan/2021 18:23'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'I'		13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered	System	13 Jan 2021 23:22:36
'USA-US075-2021-MRNA-1273-P301000001'		

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:59
DataPoint Verified.		02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'Jennifer'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
User entered 'Briskin' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:01
DataPoint Verified.		02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'Gaston'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'OH'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'US'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Mar 2021 19:43:13
User entered '2'	System	11 Feb 2021 21:36:50
User entered '1'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:32:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
User entered '11/Feb/2021 16:36'	System	11 Feb 2021 21:36:50

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:32:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 21:36:55
User entered 'I'		11 Feb 2021 21:36:50

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered	System	13 Jan 2021 23:22:36
'USA-US075-2021-MRNA-1273-P301000001'		

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'No (N)'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
Signature has been broken.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
User entered 'Toby' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:59
DataPoint Verified.		02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'Jennifer'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
Signature has been broken.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
User entered 'Briskin' reason for change: Data Entry Error	Cassie Uminski (b) (4)	15 Apr 2021 14:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:20:01
DataPoint Verified.		02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'Gaston'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'OH'	System	13 Jan 2021 23:22:36

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:57
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:19

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:22:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:23:44
User entered 'US'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Mar 2021 19:43:13
User entered '2'	System	11 Feb 2021 21:36:50
User entered '1'	System	13 Jan 2021 23:23:39

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:32:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User entered '19/Mar/2021 14:43'	System	19 Mar 2021 19:43:13

US3182145

Folder: SAE USA-US075-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:32:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:19:56
User signature succeeded.	Mary Beth Manning	20 Mar 2021 20:42:41
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 19:43:13