

US3342343 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

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US3342343

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 22:12:03

Generated On: 09 Jun 2021 17:08:26

[Participant ID](#)

US3342343

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

US3342343

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 OCT 2020

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

Folder OID SCRN

US3342343

Folder: Screening

Form: Demographics

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
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	True
Not reported	False

US3342343

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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

Month and Year of Informed Consent (derived) OCT 2020

Year of Informed Consent (derived) 2020

Protocol Version
Amendment 1
Amendment 2
Amendment 3
Amendment 4
Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail
Withdrew Consent
Inclusion/Exclusion
Cohort Full
Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 29 Mar 2021 22:12:08

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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) 29 Mar 2021 22:12:08

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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) 29 Mar 2021 22:12:08

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Condition	HYSTERECTOMY (DUE TO UTERINE FIBROIDS)
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Condition	FIBROIDS OF THE UTERUS
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 22:12:08

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Condition	LEFT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3342343

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Condition	LEFT HIP SPORTS INDUCED INJURY
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Condition	HEADACHES
Start date (dd MMM yyyy)	06 SEP 2019
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)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 6 OCT 2020

Time of assessment (*00:00-23:59*) 13:49 (24 HR)

Vital Signs Date and Time (derived) 6 OCT 2020 13:49

Height (*xxx.x*) 166.5 cm

Weight (*xxx.x*) 85.8 kg

BMI (*xxx.x*) 30.94987 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) 98.4 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) 51 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 12 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 146 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 93 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

6 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*) 6 OCT 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 1985

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Mar 2021 22:12:08

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Mar 2021 22:12:08

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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)	True
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) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 OCT 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

What was the date of randomization? (dd MMM yyyy) 12 OCT 2020

What was the participant's randomization number? 116224

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

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) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

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 (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:21 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:21
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:31 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 13:31
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

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) 12 OCT 2020

What was the treatment time? (00:00-23:59) 12:37 (24 HR)

Treatment Date and Time (derived) 12 OCT 2020 12:37

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) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 OCT 2020

Collection time (*00:00-23:59*) 12:17 (24 HR)

Collection date and time (derived) 12 OCT 2020 12:17

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Collection date (<i>dd MMM yyyy</i>)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:20	12 OCT 2020 12:20
Nasopharyngeal Swab 2	No		

US3342343

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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 97.1 °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 12 OCT 2020 13:35

PC Open Date & Time 12 OCT 2020 12:57

PC Close Date & Time 12 OCT 2020 15:27

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp 13 OCT 2020 10:54
PC Open Date & Time 12 OCT 2020 16:22
PC Close Date & Time 13 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 OCT 2020 10:00
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

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 _____

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 _____

To **PREVENT** pain or fever from occurring _____

PC Time Stamp _____

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:26

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** 96.8 °F

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

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

PC Time Stamp 16 OCT 2020 11:22

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

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 _____
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 _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 16 OCT 2020 12:00
PC Close Date & Time 17 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 OCT 2020 12:01
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 OCT 2020 10:26
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	12 OCT 2020 13:36
PC Open Date & Time	12 OCT 2020 12:57
PC Close Date & Time	12 OCT 2020 15:27

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

13 OCT 2020 10:55

PC Open Date & Time

12 OCT 2020 16:22

PC Close Date & Time

13 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	14 OCT 2020 10:01
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 3

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

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

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

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

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 4

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	16 OCT 2020 11:22
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 5

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

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

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

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

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 6

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

17 OCT 2020 12:01

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 7

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	19 OCT 2020 10:27
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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

No

Yes

PC Time stamp	12 OCT 2020 13:38
PC Open Date & Time	12 OCT 2020 12:57
PC Close Date & Time	12 OCT 2020 15:27

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

No

Yes

PC Time stamp	13 OCT 2020 10:56
PC Open Date & Time	12 OCT 2020 16:22
PC Close Date & Time	13 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

	Yes <input type="checkbox"/>
PC Time stamp	14 OCT 2020 10:02
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

Yes

PC Time stamp

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

	Yes <input type="checkbox"/>
PC Time stamp	16 OCT 2020 11:23
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

Yes

PC Time stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

	Yes <input type="checkbox"/>
PC Time stamp	17 OCT 2020 12:02
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

	Yes <input type="checkbox"/>
PC Time stamp	19 OCT 2020 10:27
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp 20 OCT 2020 09:10

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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

PC Time Stamp 21 OCT 2020 00:00

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

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

PC Time Stamp

22 OCT 2020 01:00

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

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

PC Time Stamp 23 OCT 2020 10:26

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

20 OCT 2020 09:10

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

21 OCT 2020 00:00

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None

FATIGUE

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

22 OCT 2020 01:00

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp 20 OCT 2020 09:10

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

21 OCT 2020 00:00

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

22 OCT 2020 01:00

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

23 OCT 2020 10:27

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

23 OCT 2020 22:35

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp 25 OCT 2020 12:00

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp 20 OCT 2020 09:10

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

21 OCT 2020 00:01

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

22 OCT 2020 01:00

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

23 OCT 2020 10:26

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

23 OCT 2020 22:35

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

25 OCT 2020 12:00

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**

None

ACHES IN SEVERAL JOINTS

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

27 OCT 2020 09:14

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 09:11
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 00:01
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 01:00
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 10:26
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 22:35
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 12:00
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 OCT 2020 09:14
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*)

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

Comments CONTACT NOT MADE DUE TO
CONVALESCENT PERIOD.
If Contact Not Made, please provide Comments SAFETY CALL DAY 15 WAS
SKIPPED.

US3342343

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 9 NOV 2020

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

Folder OID VISIT2

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

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 (<i>dd MMM yyyy</i>)	9 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:33 (24 HR)
Vital Signs Date and Time (derived)	9 NOV 2020 09:33
Temperature (<i>xxx.x</i>)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

Timepoint Pre-Dose
Post-Dose

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

Time of assessment (*00:00-23:59*) _____

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

US3342343

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

9 NOV 2020

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

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was study treatment given? Yes
No

If No, reason not given

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

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

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 09 NOV 2020

Collection time (*00:00-23:59*) 10:43 (24 HR)

Collection date and time (derived) 09 NOV 2020 10:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Collection date (<i>dd MMM yyyy</i>)			09 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:45	09 NOV 2020 10:45
Nasopharyngeal Swab 2	No		

US3342343

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:25

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 DEC 2020

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

Folder OID VISIT3

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	10:14 (24 HR)
Vital Signs Date and Time (derived)	04 DEC 2020 10:14
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	55 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342343

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

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.

US3342343

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	4 DEC 2020
Collection time (<i>00:00-23:59</i>)	10:35 (24 HR)
Collection date and time (derived)	4 DEC 2020 10:35

US3342343

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:06:26

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 61

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 15:58:29

Patient Cloud Open Date & Time 09 DEC 2020 00:01

Patient Cloud Close Date & Time 13 DEC 2020 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 68
Have 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	20 DEC 2020 12:40:35
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 75
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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	26 DEC 2020 18:19:06
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 22:04:21
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 89

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 96
Have 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 05:13:47
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 20 JAN 2021 19:06:11

Patient Cloud Open Date & Time 20 JAN 2021 00:01

Patient Cloud Close Date & Time 24 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 27 JAN 2021 00:01:27

Patient Cloud Open Date & Time 27 JAN 2021 00:01

Patient Cloud Close Date & Time 31 JAN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 11:02:24
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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	11 FEB 2021 15:46:56
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Have 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):

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

Date and time of submission 19 FEB 2021 22:49:36

Patient Cloud Open Date & Time 17 FEB 2021 00:01

Patient Cloud Close Date & Time 21 FEB 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#) 28 FEB 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 145

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 14 MAR 2021 19:07:28

Patient Cloud Open Date & Time 10 MAR 2021 00:01

Patient Cloud Close Date & Time 14 MAR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 17 MAR 2021 07:59:20

Patient Cloud Open Date & Time 17 MAR 2021 00:01

Patient Cloud Close Date & Time 21 MAR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 166

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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	09 APR 2021 17:39:17
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 21 APR 2021 14:01:12

Patient Cloud Open Date & Time 21 APR 2021 00:01

Patient Cloud Close Date & Time 25 APR 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	19 MAY 2021 00:01
Patient Cloud Close Date & Time	23 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2021 00:01
Patient Cloud Close Date & Time	30 MAY 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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
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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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
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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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
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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 10 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	03 NOV 2021 00:01
Patient Cloud Close Date & Time	07 NOV 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	24 NOV 2021 00:01
Patient Cloud Close Date & Time	28 NOV 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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
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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	09 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 467

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	19 JAN 2022 00:01
Patient Cloud Close Date & Time	23 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 30 JAN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	02 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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
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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	13 FEB 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 27 FEB 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	13 MAR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 544

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

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

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

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

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	20 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	27 APR 2022 00:01
Patient Cloud Close Date & Time	01 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 593

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 614

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 628

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 656

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 705

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#) 09 OCT 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 16 OCT 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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
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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#) 13 NOV 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission	
Patient Cloud Open Date & Time	23 NOV 2022 00:01
Patient Cloud Close Date & Time	27 NOV 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

[Patient Cloud Close Date & Time](#)

04 DEC 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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°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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

Patient Cloud Open Date & Time	07 DEC 2022 00:01
Patient Cloud Close Date & Time	11 DEC 2022 23:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 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

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 14 DEC 2022 00:01

[Patient Cloud Close Date & Time](#) 18 DEC 2022 23:59

US3342343

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:08:26

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		08 MAR 2021 16:14:03

US3342343

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 4 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 15:57:06

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:57:06

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	VISIT4

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 APR 2021
Time of assessment (<i>00:00-23:59</i>)	13:29 (24 HR)
Vital Signs Date and Time (derived)	27 APR 2021 13:29
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>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3342343

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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.

US3342343

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 22:18:06

Generated On: 09 Jun 2021 17:08:26

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 27 APR 2021

Collection time (*00:00-23:59*) 14:02 (24 HR)

Collection date and time (derived) 27 APR 2021 14:02

US3342343

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

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 _____

US3342343

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Data signed: (b) (4) 29 Mar 2021 22:12:06

Generated On: 09 Jun 2021 17:08:26

Date of Contact	11 MAR 2021
Time of Contact	13:30
Date and Time of Contact (derived)	11 MAR 2021 13:30
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input checked="" type="checkbox"/> Safety Call <input type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Symptom Day

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date		07 MAR 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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

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

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

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

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

Shortness of Breath

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

Difficulty Breathing

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

	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"/>

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Symptom Day

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

	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 MAR 2021
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	99.0 F
-------------	--------

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

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

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

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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 11 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

	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 MAR 2021
------	-------------

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

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

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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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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 11 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

	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 MAR 2021
------	-------------

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

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

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

Temperature	98.9 F
-------------	--------

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

Cough	None	<input 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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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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 11 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

	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 MAR 2021
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

Date	15 MAR 2021
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

Date 16 MAR 2021

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 96.8 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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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

Date	17 MAR 2021
------	-------------

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

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

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

Temperature	98.9 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Mar 2021 22:12:06

Generated On: 09 Jun 2021 17:08:26

Date of Visit 11 MAR 2021

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

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

Date of Test 11 MAR 2021

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Mar 2021 22:12:06

Generated On: 09 Jun 2021 17:08:26

Date of Contact	22 OCT 2020
Time of Contact	11:35
Date and Time of Contact (derived)	22 OCT 2020 11:35
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input checked="" type="checkbox"/> Safety Call <input type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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 OCT 2020
------	-------------

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

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

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

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

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

Cough	None	<input 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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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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 OCT 2020
------	-------------

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

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

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

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

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

Cough	None	<input 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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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 OCT 2020
------	-------------

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

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

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

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

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

Cough	None	<input 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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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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 OCT 2020
------	-------------

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

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

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

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

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

Cough	None	<input 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

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EAB) (1725)

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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 OCT 2020
------	-------------

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

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

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

Temperature	96.4 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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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 OCT 2020
------	-------------

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

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

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

Temperature	98.0 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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"/>

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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 OCT 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	96.0 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003 EAB) (1725)	406 of 2739
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US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Mar 2021 22:12:06

Generated On: 09 Jun 2021 17:08:26

Date of Visit 22 OCT 2020

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

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

Date of Test 22 OCT 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Mar 2021 22:12:06

Generated On: 09 Jun 2021 17:08:26

[Generate Next COVID-19 Assessment](#)

Yes

No

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	24 OCT 2020
Day 5	Yes	26 OCT 2020
Day 7	Yes	28 OCT 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 MAR 2021
Day 5	Yes	15 MAR 2021
Day 7	Yes	17 MAR 2021
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:53 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:53
Height (<i>xxx.x</i>)	166.5 cm
Weight (<i>xxx.x</i>)	85.8 kg
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3342343

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3342343

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

22 OCT 2020

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 MAR 2021

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

Folder OID SICKD1

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:57 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 13:57
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3342343

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3342343

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Apr 2021 15:57:06

Generated On: 09 Jun 2021 17:08:26

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

11 MAR 2021

US3342343

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

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 JAN 2021

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

Folder OID UNBLND_DECIDE

US3342343

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

Form: Unblinding

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3342343

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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

US3342343

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 13:20
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	077 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	097 mmHg
Diastolic Blood Pressure units	MMHG

US3342343

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:35
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	056 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	087 mmHg
Diastolic Blood Pressure units	MMHG

US3342343

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

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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.

US3342343

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

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 13:58 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 13:58

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

US3342343

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 JAN 2021

Collection time (*00:00-23:59*) 13:48 (24 HR)

Collection date and time (derived) 14 JAN 2021 13:48

US3342343

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 JAN 2021

Collection time (*00:00 - 23:59*) 13:50

Collection Date and Time (derived) 14 JAN 2021 13:50

US3342343

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

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 08 FEB 2021

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

Folder OID OLD29

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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 (<i>dd MMM yyyy</i>)	08 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	14:44 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 14:44
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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 (<i>dd MMM yyyy</i>)	08 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	15:53 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 15:53
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	55 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3342343

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

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.

US3342343

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 08 FEB 2021

What was the treatment time? (00:00-23:59) 15:23 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 15:23

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

What was the frequency of the study treatment dosing? ONCE

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

US3342343

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3342343

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342343

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:57 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 13:57
Temperature (<i>xxx.x</i>)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3342343

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:57:06

Generated On: 09 Jun 2021 17:08:26

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3342343

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 22:12:08

Generated On: 09 Jun 2021 17:08:26

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 11 MAR 2021

Collection time (*00:00-23:59*) 14:22 (24 HR)

Collection date and time (derived) 11 MAR 2021 14:22

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 12 Apr 2021 15:57:06

Generated On: 09 Jun 2021 17:08:26

Visit Date	08 FEB 2021
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	False
---------------	-------

Vital Signs	False
-------------	-------

Immunogenicity Assessment	True
---------------------------	------

Pregnancy Test	False
----------------	-------

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Immunogenicity Assessment**

Data signed: (b) (4) **12 Apr 2021 15:57:06**

Generated On: **09 Jun 2021 17:08:26**

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 08 FEB 2021

Collection time (*00:00-23:59*) 15:15 (24 HR)

Collection date and time (derived) 08 FEB 2021 15:15

US3342343

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:44:57

Generated On: 09 Jun 2021 17:08:26

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

AEID USA-US203-2021-MRNA-1273-P30
1000014

Adverse event WORSENING OF
OSTEOARTHRITIS OF
CERVICAL SPINE

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 19 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 02 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 31 MAR 2021

Hospital Discharge Date (dd MMM yyyy) 02 APR 2021

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

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	True
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

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

PT REPORTS SURGERY ON
31MAR2021. PT WAS
HOSPITALIZED FOR 2 DAYS. PT
PRESCRIBED A MUSCLE SPASM
AND PAIN MEDICATION (NAME
AND DOSAGE UNKNOWN). PT
STATES SHE HAD SURGERY ON
CERVICAL DISC (UNSURE OF
EXACT TERMINOLOGY FOR
TYPE OF SURGERY).
DOCU-SIGN SENT TO OBTAIN
MEDICAL RECORDS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

AEID

Adverse event

NEW ONSET OF SYMMETRICAL
SYNOVITIS OF HANDS AND
FEET

Was this a medically-attended AE?

Yes
No

Was this a Solicited Adverse Reaction?

Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes
No

Start date (dd MMM yyyy)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes
No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

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 <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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	SUBJECT REPORTS WORSENING OF OSTEOARTHRITIS IN HIPS, WRISTS, AND ANKLES FOR THE PAST 2 WEEKS. SHE REPORTS USING TORADOL TO TREAT.
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)	

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

AEID

Adverse event

ACUTE VIRAL INFECTION

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes

No

Start date (dd MMM yyyy)

13 OCT 2020

Start time (00:00-23:59)

13:38 (24 HR)

AE start date and time (derived)

13 OCT 2020 13:38

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

28 OCT 2020

End time (00:00-23:59)

16:49 (24 HR)

AE End Date and Time (derived)

28 OCT 2020 16:49

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT REPORTED FATIGUE, MUSCLE ACHES, AND HA ONGOING PAST DAY 7 POST STUDY VACCINE ONE. BROUGHT IN FOR ILLNESS VISIT. COVID NEGATIVE. SYMPTOMS RESOLVED.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

AEID	
Adverse event	HYPERTENSION
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 type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

AEID	
Adverse event	ALLERGIC RHINITIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 MAR 2021
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)	15 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

AEID _____
Adverse event _____ OSTEOARTHRITIS AND
POST-OPERATIVE PAIN AFTER
SURGERY

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 02 APR 2021

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

AE start date and time (derived) _____

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) _____

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

AE End Date and Time (derived) _____

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy) _____

Hospital Discharge Date (dd MMM yyyy) _____

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU _____

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EAB) (1725)

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

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 <input type="radio"/> 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Mar 2021 13:40:56

Generated On: 09 Jun 2021 17:08:26

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

Yes

No

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

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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*) 31 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Name of Medication TORADOL

Prophylaxis Yes
No

Indication NEW ONSET OF SYMMETRICAL
SYNOVITIS OF HANDS AND
FEET

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	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)	31 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	_____
Interval Dosage Unit Number (derived)	_____
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input type="checkbox"/>

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Name of Medication CORTICOSTEROID

Prophylaxis Yes
No

Indication CERVICAL DISC DISEASE AE

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

DOSE *SUBJECT DID NOT
KNOW THE SPECIFIC DETAILS
OF THE STEROID INJECTION
(DRUG NAME, DOSAGE).
REPORTS LANGUAGE BARRIER
BETWEEN THEMSELVES AND
THEIR PRIMARY CARE
PHYSICIAN WHO
ADMINISTERED THE INJ.

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

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:42:58

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If frequency is Other, specify _____

Route of administration

Oral

Topical

Subcutaneous

Transdermal

Intraocular

Intramuscular

Respiratory (Inhalation)

Intralesional

Intraperitoneal

Nasal

Vaginal

Rectal

Intravenous

Intravenous Bolus

Intravenous Drip

Other

If route of administration is Other, specify _____ EPIDURAL

Start date (dd MMM yyyy) 21 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 21 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Name of Medication LISINOPRIL

Prophylaxis Yes
No

Indication HYPERTENSION AE

Dose per administration 2.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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*) 04 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication ALLERGIC RHINITIS AE

Dose per administration 600

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

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*) 11 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 11 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication OSTEOARTHRITIS AND
POSTOPERATIVE PAIN AFTER
SURGERY

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

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) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 02 APR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3342343

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 22:12:06

Generated On: 09 Jun 2021 17:08:26

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3342343

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Mar 2021 22:12:06

Generated On: 09 Jun 2021 17:08:26

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
19 OCT 2020	MRI - CERVICAL SPINE	Adverse Event	

US3342343

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 29 Mar 2021 22:12:07

Generated On: 09 Jun 2021 17:08:26

Date of dosing discontinuation (dd MMM yyyy) 09 NOV 2020

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Due to SARS-COV-2

Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE#2

US3342343

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:08:26

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

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

SAEID	USA-US203-2021-MRNA-1273-P30 1000014
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

SAEID	USA-US203-2021-MRNA-1273-P30 1000014
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	07/APR/2021 12:36
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

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

SAEID	USA-US203-2021-MRNA-1273-P30 1000014
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	_____
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.	False

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 16:42:58

Generated On: 09 Jun 2021 17:08:26

SAEID	USA-US203-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	27/APR/2021 15:56
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.	<input checked="" type="checkbox"/> True

Audit

US3342343 (Prod: Tekton Research- Austin)

US3342343

Form: Participant Creation

Generated On: 09 Jun 2021 17:08:26

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:20:11
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'US3342343'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Oct 2020 19:02:49

US3342343

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:19:32

US3342343

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '06 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Oct 2020 19:02:51

US3342343

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:19:32

US3342343

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'SCRN'	System	06 Oct 2020 20:19:32

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Oct 2020 19:02:52

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '61'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'YEARS'	System	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '61'	System	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Female (F)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '1'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:08

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '6 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Oct 2020'	System	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '2020'	System	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Amendment 4 (4)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:20:56

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Oct 2020 19:02:51

US3342343

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '1'	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:08:26

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:08:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:21:12

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of cervical spine - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 14:09:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 14:09:14
Data point term sent to Coder	System	22 Mar 2021 16:40:35
Coding entries removed.	Stefanie Mott (b) (4)	22 Mar 2021 16:40:33
User entered 'OSTEOARTHRITIS OF THE CERVICAL SPINE' reason for change: Data Entry Error	Stefanie Mott (b) (4)	22 Mar 2021 16:40:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis spinal - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 20:24:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 20:24:27
Data point term sent to Coder	System	06 Oct 2020 20:23:39
User entered 'Osteoarthritis of the spine'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 2010'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 2010'	System	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '2010'	System	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered empty.	System	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered empty.	System	06 Oct 2020 20:22:37

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 00:15:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 00:15:48
Data point term sent to Coder	System	06 Oct 2020 20:24:45
User entered 'Hysterectomy (due to uterine fibroids)'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 1985'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 1985'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 1985'	System	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '1985'	System	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 1985'	System	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '1985'	System	06 Oct 2020 20:24:38

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	06 Oct 2020 20:26:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 20:26:22
Data point term sent to Coder	System	06 Oct 2020 20:25:47
User entered 'Fibroids of the uterus'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 1985'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 1985'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 1985'	System	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '1985'	System	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 1985'	System	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '1985'	System	06 Oct 2020 20:25:01

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 20:28:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 20:28:17
Data point term sent to Coder	System	06 Oct 2020 20:27:55
User entered 'LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	06 Oct 2020 20:27:07
Data point term sent to Coder	System	06 Oct 2020 20:25:47
User entered 'Left hip knee replacement'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 2003'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 2003'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 2003'	System	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '2003'	System	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 2003'	System	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '2003'	System	06 Oct 2020 20:25:43

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Sports injury, LLT: Sports injury - version MedDRA\23.0.	Coder Import (b) (4)	11 Oct 2020 15:16:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Oct 2020 15:16:27
Data point term sent to Coder	System	06 Oct 2020 20:26:52
User entered 'Left hip sports induced injury'	Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 2003'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 2003'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 2003'	System	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '2003'	System	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 2003'	System	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '2003'	System	06 Oct 2020 20:26:37

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 17:45:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 17:45:37
Data point term sent to Coder	System	23 Oct 2020 17:44:58
User entered 'Headaches'	Darrell O'Brien (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '06 Sep 2019'	(b) (4) Darrell O'Brien (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Darrell O'Brien (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Darrell O'Brien (b) (4)	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Sep 2019'	System	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '2019'	System	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered empty.	System	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered empty.	System	23 Oct 2020 17:44:34

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
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)	10 Nov 2020 05:49:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 05:49:27
Data point term sent to Coder	System	09 Nov 2020 21:13:38
User entered 'Osteoarthritis of bilateral hips and bilateral wrists'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 2010'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'Jan 2010'	System	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '2010'	System	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered empty.	System	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered empty.	System	09 Nov 2020 21:13:20

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '6 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '13:49'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '6 Oct 2020 13:49'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '166.5' cm	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23
DataPoint set to visible.	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '85.8' kg	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23
DataPoint set to visible.	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered '30.94987'	System	06 Oct 2020 20:28:23
DataPoint set to visible.	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'kg/m2'	System	06 Oct 2020 20:28:23
DataPoint set to visible.	System	06 Oct 2020 20:21:03

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Oct 2020 20:28:30
User entered '98.4' F reason for change: Data Entry Error	System	06 Oct 2020 20:28:30
User entered '98.4' F reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Oct 2020 20:28:23
User entered '98.4' (non-conformant).	System	06 Oct 2020 20:28:23
User entered '98.4' (non-conformant).	Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Oral (Oral)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '51'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'bpm'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '12'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'breaths/min'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '146'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'mmHg'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '93'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User entered 'mmHg'	System	06 Oct 2020 20:28:23

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15

US3342343

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15

US3342343

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:57

US3342343

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '6 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:28:57

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '6 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:08:26

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:08:26

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:08:26

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:08:26

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'un UNK 1985'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:08:26

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:08:26

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:08:26

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:29:33

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

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 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '1'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:22:15
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	06 Oct 2020 20:35:51

US3342343

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:03

US3342343

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:03

US3342343

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:03

US3342343

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'VISIT1'	System	12 Oct 2020 16:52:03

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 17:03:32

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '116224'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 17:03:32

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	13 Feb 2021 00:06:25
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 17:03:32

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

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)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

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)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:20

US3342343

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:26

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:52:20
DataPoint set to visible.	System	06 Oct 2020 20:20:56

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 17:31:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 17:31:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:31:14
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:08:33
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '11:21' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered '12 Oct 2020 11:21'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '98.6' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '63' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'bpm'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '15' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'breaths/min'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '138' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'mmHg'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '88' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:31:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'mmHg'	System	12 Oct 2020 17:31:14
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 18:43:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 18:43:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Oct 2020 18:43:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 17:08:33
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:43:20
User entered empty.	Morgan Schulle (b) (4)	12 Oct 2020 17:08:33
	(b) (4)	
	(b) (4), (b) (6)	

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '13:31' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:43:20
User entered empty.	Morgan Schulle (b) (4)	12 Oct 2020 17:08:33
	(b) (4), (b) (6)	

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered '12 Oct 2020 13:31'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '97.1' F reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:43:20
User entered empty.	Morgan Schulle (b) (4)	12 Oct 2020 17:08:33
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:43:20
User entered empty.	Morgan Schulle (b) (4)	12 Oct 2020 17:08:33
	(b) (4), (b) (6)	

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '60' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:43:20
User entered empty.	Morgan Schulle (b) (4)	12 Oct 2020 17:08:33
	(b) (4), (b) (6)	

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'bpm'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '16' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:43:20
User entered empty.	Morgan Schulle (b) (4)	12 Oct 2020 17:08:33
	(b) (4)	
	(b) (4), (b) (6)	

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'breaths/min'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '139' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:43:20
User entered empty.	Morgan Schulle (b) (4)	12 Oct 2020 17:08:33
	(b) (4)	
	(b) (4), (b) (6)	

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'mmHg'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '91' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:43:20
User entered empty.	Morgan Schulle (b) (4)	12 Oct 2020 17:08:33
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'mmHg'	System	12 Oct 2020 18:43:20
User entered empty.	System	12 Oct 2020 17:08:33

US3342343

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:44

US3342343

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:08:44

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Morgan Schulle (b) (4)	12 Oct 2020 18:29:26

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

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)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Morgan Schulle (b) (4)	12 Oct 2020 18:29:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12 Oct 2020'	(b) (4) Morgan Schulle (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12:37'	(b) (4) Morgan Schulle (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered '12 Oct 2020 12:37'	System	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) Morgan Schulle (b) (4)	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'ONCE'	System	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 18:29:26

US3342343

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 14:09:01

US3342343

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12 Oct 2020'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 14:09:01

US3342343

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12:17'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 14:09:01

US3342343

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered '12 Oct 2020 12:17'	System	28 Oct 2020 14:09:01

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12 Oct 2020'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '12:20'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered '12 Oct 2020 12:20'	System	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered empty.	System	28 Oct 2020 14:08:41

US3342343

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:29:58

US3342343

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered '1'	System	12 Oct 2020 17:29:58

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:35:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0a778428-3fc9-4249-a5be-402a53aa323f'	System	12 Oct 2020 18:35:48
User entered 'Yes (Y)'	System	12 Oct 2020 18:35:48

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:35:31', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0a778428-3fc9-4249-a5be-402a53aa323f' User entered '97.1'	System	12 Oct 2020 18:35:48
	System	12 Oct 2020 18:35:48

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:35:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0a778428-3fc9-4249-a5be-402a53aa323f'	System	12 Oct 2020 18:35:48
User entered 'No (N)'	System	12 Oct 2020 18:35:48

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:35:46', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0a778428-3fc9-4249-a5be-402a53aa323f' User entered '12 Oct 2020 13:35'	System	12 Oct 2020 18:35:48
	System	12 Oct 2020 18:35:48

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 12:57'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 15:27'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:54:18', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '57e9d57d-6761-48a9-a486-e372a3e0d018'	System	13 Oct 2020 15:54:45
User entered 'Yes (Y)'	System	13 Oct 2020 15:54:45

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:54:26', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '57e9d57d-6761-48a9-a486-e372a3e0d018'	System	13 Oct 2020 15:54:45
User entered '97.8'	System	13 Oct 2020 15:54:45

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:54:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '57e9d57d-6761-48a9-a486-e372a3e0d018'	System	13 Oct 2020 15:54:45
User entered 'No (N)'	System	13 Oct 2020 15:54:45

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:54:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '57e9d57d-6761-48a9-a486-e372a3e0d018' User entered '13 Oct 2020 10:54'	System	13 Oct 2020 15:54:45
	System	13 Oct 2020 15:54:45

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 16:22'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 2'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:07', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0e2f07cb-aa94-40f3-bd19-50284e99d77e'	System	14 Oct 2020 15:00:38
User entered 'Yes (Y)'	System	14 Oct 2020 15:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0e2f07cb-aa94-40f3-bd19-50284e99d77e'	System	14 Oct 2020 15:00:38
User entered '96.8'	System	14 Oct 2020 15:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0e2f07cb-aa94-40f3-bd19-50284e99d77e'	System	14 Oct 2020 15:00:38
User entered 'No (N)'	System	14 Oct 2020 15:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:34', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0e2f07cb-aa94-40f3-bd19-50284e99d77e'	System	14 Oct 2020 15:00:38
User entered '14 Oct 2020 10:00'	System	14 Oct 2020 15:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 3'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 4'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:20:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '37f3735f-7c37-4130-af54-004d381822ba'	System	16 Oct 2020 16:22:31
User entered 'Yes (Y)'	System	16 Oct 2020 16:22:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:14', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '37f3735f-7c37-4130-af54-004d381822ba'	System	16 Oct 2020 16:22:31
User entered '96.8'	System	16 Oct 2020 16:22:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '37f3735f-7c37-4130-af54-004d381822ba'	System	16 Oct 2020 16:22:31
User entered 'No (N)'	System	16 Oct 2020 16:22:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '37f3735f-7c37-4130-af54-004d381822ba'	System	16 Oct 2020 16:22:31
User entered '16 Oct 2020 11:22'	System	16 Oct 2020 16:22:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 5'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 6'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:00:41', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '98b14f2a-6a9e-4469-997b-ce80dcf41ea9'	System	17 Oct 2020 17:01:31
User entered 'Yes (Y)'	System	17 Oct 2020 17:01:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:00:58', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '98b14f2a-6a9e-4469-997b-ce80dcf41ea9'	System	17 Oct 2020 17:01:31
User entered '97.8'	System	17 Oct 2020 17:01:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:03', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '98b14f2a-6a9e-4469-997b-ce80dcf41ea9'	System	17 Oct 2020 17:01:31
User entered 'No (N)'	System	17 Oct 2020 17:01:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '98b14f2a-6a9e-4469-997b-ce80dcf41ea9'	System	17 Oct 2020 17:01:31
User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:31

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 7'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:25:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c50002db-c848-4375-9feb-033d4b01d422'	System	19 Oct 2020 15:26:35
User entered 'Yes (Y)'	System	19 Oct 2020 15:26:35

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:26:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c50002db-c848-4375-9feb-033d4b01d422'	System	19 Oct 2020 15:26:35
User entered '97.8'	System	19 Oct 2020 15:26:35

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:26:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c50002db-c848-4375-9feb-033d4b01d422'	System	19 Oct 2020 15:26:35
User entered 'No (N)'	System	19 Oct 2020 15:26:35

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:26:31', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c50002db-c848-4375-9feb-033d4b01d422'	System	19 Oct 2020 15:26:35
User entered '19 Oct 2020 10:26'	System	19 Oct 2020 15:26:35

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:36:05', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:36:34', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered 'No (N)'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:36:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered 'No (N)'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:36:55', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered 'None (1)'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:36:59', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd8130637-f17e-4b78-a797-6ad2e23af3e8'	System	12 Oct 2020 18:37:01
User entered '12 Oct 2020 13:36'	System	12 Oct 2020 18:37:01

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 12:57'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 15:27'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:55:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered 'None (1)'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:55:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered 'No (N)'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:55:33', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered 'No (N)'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:55:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered 'None (1)'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:55:52', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '241f8c2a-daac-4fad-b6de-f29e2b3d2308'	System	13 Oct 2020 15:55:55
User entered '13 Oct 2020 10:55'	System	13 Oct 2020 15:55:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 16:22'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 2'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered 'None (1)'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:00:59', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered 'No (N)'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:11', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered 'No (N)'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8'	System	14 Oct 2020 15:01:23
User entered 'None (1)'	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:19', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a1143904-4e2a-4b51-9c61-0a870f9689e8' User entered '14 Oct 2020 10:01'	System	14 Oct 2020 15:01:23
	System	14 Oct 2020 15:01:23

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 3'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 4'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:36', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered 'None (1)'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered 'No (N)'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered 'No (N)'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:52', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered 'None (1)'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:22:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cc4620ba-2464-42b0-b37d-d0411d81e6c0'	System	16 Oct 2020 16:22:59
User entered '16 Oct 2020 11:22'	System	16 Oct 2020 16:22:59

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 5'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 6'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:33', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered 'None (1)'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:37', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered 'No (N)'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered 'No (N)'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:49', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered 'None (1)'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:52', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b85b8511-c23b-42d2-b1e3-ab27926e3f9d'	System	17 Oct 2020 17:01:55
User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:55

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 7'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:26:58', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered 'None (1)'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:02', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered 'No (N)'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:05', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered 'No (N)'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered 'None (1)'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:14', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b653248-3ef5-48a2-bd41-d9776fa72f3b'	System	19 Oct 2020 15:27:20
User entered '19 Oct 2020 10:27'	System	19 Oct 2020 15:27:20

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:37:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'None (0)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:37:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:37:49', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:04', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'None (0)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:08', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'None (0)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered 'No (N)'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-12T13:38:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3bd41a9b-5a8d-461d-a19a-f118a86aa5a8'	System	12 Oct 2020 18:38:48
User entered '12 Oct 2020 13:38'	System	12 Oct 2020 18:38:48

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 12:57'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 15:27'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:10', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'No interference with activity (1)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'No interference with activity (1)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'Some interference with activity (2)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'Some interference with activity (2)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:30', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'None (0)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:34', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'None (0)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered 'No (N)'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-13T10:56:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '147b3284-e9fb-4331-b5b5-44094c67b646'	System	13 Oct 2020 15:56:45
User entered '13 Oct 2020 10:56'	System	13 Oct 2020 15:56:45

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '12 Oct 2020 16:22'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 2'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'None (0)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'No interference with activity (1)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:36', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'No interference with activity (1)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:41', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'No interference with activity (1)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'None (0)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:48', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'None (0)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:01:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9'	System	14 Oct 2020 15:02:06
User entered 'No (N)'	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-14T10:02:01', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ff72b02-f85c-4e83-bbf6-5e7e1818c4b9' User entered '14 Oct 2020 10:02'	System	14 Oct 2020 15:02:06
	System	14 Oct 2020 15:02:06

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 3'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 4'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:23', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'Some interference with activity (2)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'Some interference with activity (2)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'None (0)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'None (0)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:40', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1'	System	16 Oct 2020 16:23:49
User entered 'No (N)'	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-16T11:23:45', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5ac4250d-51a0-40dc-b3c7-e3a5bddfcfd1' User entered '16 Oct 2020 11:23'	System	16 Oct 2020 16:23:49
	System	16 Oct 2020 16:23:49

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 5'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 6'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:01:58', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'None (0)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'None (0)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:17', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:21', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'None (0)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'None (0)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered 'No (N)'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-17T12:02:38', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '946d6e91-ecbd-4ff7-95fa-f476af44bdb5'	System	17 Oct 2020 17:02:41
User entered '17 Oct 2020 12:02'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	12 Oct 2020 18:29:26
User entered 'Day 7'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:26', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No interference with activity (1)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:30', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No interference with activity (1)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:36', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No interference with activity (1)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:39', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No interference with activity (1)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:44', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'None (0)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'None (0)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:51', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0'	System	19 Oct 2020 15:28:01
User entered 'No (N)'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-19T10:27:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f3c3f39b-0e4d-4aba-bc63-e4b012c13df0' User entered '19 Oct 2020 10:27'	System	19 Oct 2020 15:28:01
	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 18:29:26

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 8'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '73c10057-1cb7-424a-92dc-69f92898d3a8'	System	20 Oct 2020 14:10:35
User entered 'No interference with activity (1)'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '73c10057-1cb7-424a-92dc-69f92898d3a8'	System	20 Oct 2020 14:10:35
User entered '20 Oct 2020 09:10'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:23', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3d902b18-4aa6-4576-882e-389dcb7dc0da'	System	21 Oct 2020 05:00:35
User entered 'No interference with activity (1)'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:31', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '3d902b18-4aa6-4576-882e-389dcb7dc0da'	System	21 Oct 2020 05:00:35
User entered '21 Oct 2020 00:00'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	20 Oct 2020 14:10:35
User entered 'Day 10'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:05', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1e92905d-1ab1-4aaa-87c3-be7009f60423'	System	22 Oct 2020 06:00:11
User entered 'No interference with activity (1)'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1e92905d-1ab1-4aaa-87c3-be7009f60423' User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:11
	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	21 Oct 2020 05:00:35
User entered 'Day 11'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:45', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f9d27080-e837-473f-922b-303c56295e25'	System	23 Oct 2020 15:26:50
User entered 'None (0)'	System	23 Oct 2020 15:26:50

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:48', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f9d27080-e837-473f-922b-303c56295e25' User entered '23 Oct 2020 10:26'	System	23 Oct 2020 15:26:50
	System	23 Oct 2020 15:26:50

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 8'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:39', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'db006a87-97ad-4267-a5b2-e2d956ee6648'	System	20 Oct 2020 14:10:46
User entered 'No interference with activity (1)'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'db006a87-97ad-4267-a5b2-e2d956ee6648'	System	20 Oct 2020 14:10:46
User entered '20 Oct 2020 09:10'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:39', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5a04fdca-7ac1-43ca-8dc4-a7f500e49e54'	System	21 Oct 2020 05:00:48
User entered 'No interference with activity (1)'	System	21 Oct 2020 05:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:42', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5a04fdca-7ac1-43ca-8dc4-a7f500e49e54'	System	21 Oct 2020 05:00:48
User entered '21 Oct 2020 00:00'	System	21 Oct 2020 05:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	20 Oct 2020 14:10:46
User entered 'Day 10'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:21', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1e188cf7-7aeb-4fd0-81a5-73e80dbdd342'	System	22 Oct 2020 06:00:27
User entered 'None (0)'	System	22 Oct 2020 06:00:27

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1e188cf7-7aeb-4fd0-81a5-73e80dbdd342'	System	22 Oct 2020 06:00:27
User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:27

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:46

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	17 Oct 2020 17:02:41
User entered 'Day 8'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b0f40ce5-a1a3-4845-8ebe-ef7d35e8ee88'	System	20 Oct 2020 14:10:24
User entered 'No interference with activity (1)'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:20', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b0f40ce5-a1a3-4845-8ebe-ef7d35e8ee88'	System	20 Oct 2020 14:10:24
User entered '20 Oct 2020 09:10'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '6341b837-2397-4ac8-84a8-e14ee9614523'	System	21 Oct 2020 05:00:54
User entered 'No interference with activity (1)'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:50', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '6341b837-2397-4ac8-84a8-e14ee9614523'	System	21 Oct 2020 05:00:54
User entered '21 Oct 2020 00:00'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	20 Oct 2020 14:10:24
User entered 'Day 10'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:29', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '7fa61ff3-016b-40b1-b33b-a6e019dd0acc'	System	22 Oct 2020 06:00:34
User entered 'No interference with activity (1)'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '7fa61ff3-016b-40b1-b33b-a6e019dd0acc'	System	22 Oct 2020 06:00:34
User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	21 Oct 2020 05:00:54
User entered 'Day 11'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:54', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c6d164c0-de54-48fe-a730-443e0f8ada08'	System	23 Oct 2020 15:27:10
User entered 'No interference with activity (1)'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:27:05', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c6d164c0-de54-48fe-a730-443e0f8ada08' User entered '23 Oct 2020 10:27'	System	23 Oct 2020 15:27:10
	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 05:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	22 Oct 2020 06:00:34
User entered 'Day 12'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c59a35d9-7ac8-4b2c-b1d8-d227fe21a44c'	System	24 Oct 2020 03:35:41
User entered 'No interference with activity (1)'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:38', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c59a35d9-7ac8-4b2c-b1d8-d227fe21a44c'	System	24 Oct 2020 03:35:41
User entered '23 Oct 2020 22:35'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 06:00:34

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	23 Oct 2020 15:27:10
User entered 'Day 13'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 15:27:10

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	24 Oct 2020 03:35:41
User entered 'Day 14'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:25', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd3001cb4-c8e3-4d67-8e77-6d33398f642d'	System	25 Oct 2020 17:00:38
User entered 'None (0)'	System	25 Oct 2020 17:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:28', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd3001cb4-c8e3-4d67-8e77-6d33398f642d'	System	25 Oct 2020 17:00:38
User entered '25 Oct 2020 12:00'	System	25 Oct 2020 17:00:38

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	17 Oct 2020 17:02:41
User entered 'Day 8'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:50', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '12f5ba82-6d7a-440c-a21f-b29ddceea297'	System	20 Oct 2020 14:10:59
User entered 'No interference with activity (1)'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:10:55', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '12f5ba82-6d7a-440c-a21f-b29ddceea297'	System	20 Oct 2020 14:10:59
User entered '20 Oct 2020 09:10'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:00:55', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b7c7f0a-a73d-470e-a71c-bd83fb290c53'	System	21 Oct 2020 05:01:09
User entered 'No interference with activity (1)'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:01:04', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1b7c7f0a-a73d-470e-a71c-bd83fb290c53'	System	21 Oct 2020 05:01:09
User entered '21 Oct 2020 00:01'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	20 Oct 2020 14:10:59
User entered 'Day 10'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:38', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a4248cdb-d2ec-43b2-ab2e-9b55f713c1bd'	System	22 Oct 2020 06:00:48
User entered 'No interference with activity (1)'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'a4248cdb-d2ec-43b2-ab2e-9b55f713c1bd' User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:48
	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:59

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	21 Oct 2020 05:01:09
User entered 'Day 11'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:07', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '54a11abe-1a07-4a72-bfd9-f5a9720deb67'	System	23 Oct 2020 15:26:15
User entered 'No interference with activity (1)'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '54a11abe-1a07-4a72-bfd9-f5a9720deb67' User entered '23 Oct 2020 10:26'	System	23 Oct 2020 15:26:15
	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 05:01:09

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	22 Oct 2020 06:00:48
User entered 'Day 12'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:45', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0223171f-71a4-45a1-8dba-eb08ce0e9890'	System	24 Oct 2020 03:35:52
User entered 'No interference with activity (1)'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:49', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '0223171f-71a4-45a1-8dba-eb08ce0e9890'	System	24 Oct 2020 03:35:52
User entered '23 Oct 2020 22:35'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 06:00:48

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	23 Oct 2020 15:26:15
User entered 'Day 13'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	24 Oct 2020 03:35:52
User entered 'Day 14'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:33', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '632dcdfc-0fa8-4d7a-b373-d078a9d2b878'	System	25 Oct 2020 17:00:43
User entered 'No interference with activity (1)'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '632dcdfc-0fa8-4d7a-b373-d078a9d2b878'	System	25 Oct 2020 17:00:43
User entered '25 Oct 2020 12:00'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:35:52

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	25 Oct 2020 17:00:43
User entered 'Day 15'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:08:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-27T09:13:59', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '2ae36ada-a1b7-4e3d-b121-fddd0765ceae'	System	27 Oct 2020 14:14:06
User entered 'None (0)'	System	27 Oct 2020 14:14:06

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-27T09:14:02', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '2ae36ada-a1b7-4e3d-b121-fddd0765ceae' User entered '27 Oct 2020 09:14'	System	27 Oct 2020 14:14:06
	System	27 Oct 2020 14:14:06

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	17 Oct 2020 17:02:41
User entered 'Day 8'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:11:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f807875f-5a08-4fa4-b0cf-4b8968aad014'	System	20 Oct 2020 14:11:09
User entered 'No (N)'	System	20 Oct 2020 14:11:09

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-20T09:11:03', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f807875f-5a08-4fa4-b0cf-4b8968aad014'	System	20 Oct 2020 14:11:09
User entered '20 Oct 2020 09:11'	System	20 Oct 2020 14:11:09

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 17:02:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	19 Oct 2020 15:28:01
User entered 'Day 9'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:01:09', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '7ed5749d-a6c6-402a-9bc9-1f0d153f809f' User entered 'No (N)'	System	21 Oct 2020 05:01:16
	System	21 Oct 2020 05:01:16

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-21T00:01:12', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '7ed5749d-a6c6-402a-9bc9-1f0d153f809f' User entered '21 Oct 2020 00:01'	System	21 Oct 2020 05:01:16
	System	21 Oct 2020 05:01:16

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 15:28:01

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	20 Oct 2020 14:10:24
User entered 'Day 10'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '29d52f6f-a3f6-4462-b1c0-4aaa95e94d1b'	System	22 Oct 2020 06:00:54
User entered 'No (N)'	System	22 Oct 2020 06:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-22T01:00:50', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '29d52f6f-a3f6-4462-b1c0-4aaa95e94d1b' User entered '22 Oct 2020 01:00'	System	22 Oct 2020 06:00:54
	System	22 Oct 2020 06:00:54

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:24

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	21 Oct 2020 05:00:35
User entered 'Day 11'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:16', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '439d4ec3-e925-4f7c-89a5-e5d4382c7f6c'	System	23 Oct 2020 15:26:23
User entered 'No (N)'	System	23 Oct 2020 15:26:23

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T10:26:21', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '439d4ec3-e925-4f7c-89a5-e5d4382c7f6c'	System	23 Oct 2020 15:26:23
User entered '23 Oct 2020 10:26'	System	23 Oct 2020 15:26:23

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 05:00:35

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	22 Oct 2020 06:00:11
User entered 'Day 12'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:53', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1a8bdece-4f2d-4819-922a-54a81dae43e0'	System	24 Oct 2020 03:35:58
User entered 'No (N)'	System	24 Oct 2020 03:35:58

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-23T22:35:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '1a8bdece-4f2d-4819-922a-54a81dae43e0' User entered '23 Oct 2020 22:35'	System	24 Oct 2020 03:35:58
	System	24 Oct 2020 03:35:58

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 06:00:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	23 Oct 2020 15:26:15
User entered 'Day 13'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 15:26:15

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	24 Oct 2020 03:35:41
User entered 'Day 14'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:39', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cb5af3ad-8c6d-4499-8428-1071c703e93d'	System	25 Oct 2020 17:00:50
User entered 'No (N)'	System	25 Oct 2020 17:00:50

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-25T12:00:42', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'cb5af3ad-8c6d-4499-8428-1071c703e93d'	System	25 Oct 2020 17:00:50
User entered '25 Oct 2020 12:00'	System	25 Oct 2020 17:00:50

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 03:35:41

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
Data entry locked.	System	25 Oct 2020 17:00:43
User entered 'Day 15'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-27T09:14:06', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c561d88b-83a3-4cec-8729-b76a5353645a'	System	27 Oct 2020 14:14:11
User entered 'No (N)'	System	27 Oct 2020 14:14:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:08:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-10-27T09:14:08', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c561d88b-83a3-4cec-8729-b76a5353645a'	System	27 Oct 2020 14:14:11
User entered '27 Oct 2020 09:14'	System	27 Oct 2020 14:14:11

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:08:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 17:00:43

US3342343

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:08:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:05
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 17:00:43

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	20 Oct 2020 17:55:30

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '20 Oct 2020'	(b) (4) Ethan Shotton (b) (4)	20 Oct 2020 17:55:30

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	20 Oct 2020 17:55:30

US3342343

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	Ethan Shotton (b) (4)	20 Oct 2020 17:55:30

US3342343

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	20 Oct 2020 17:55:37

US3342343

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered '1'	System	20 Oct 2020 17:55:37

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	04 Nov 2020 20:33:16
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	02 Nov 2020 23:25:17
User entered 'No (N)'	Ethan Shotton (b) (4)	02 Nov 2020 23:25:17
	(b) (4)	

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	04 Nov 2020 20:21:07
User entered empty; reason for change Data Entry Error	System	04 Nov 2020 20:21:07
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4)	04 Nov 2020 20:21:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	04 Nov 2020 20:21:07
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Nov 2020 23:27:20
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	02 Nov 2020 23:27:20
answered by data change (Site from System). User entered ' 2020' (non-conformant).	System	02 Nov 2020 23:27:20
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Ethan Shotton (b) (4)	02 Nov 2020 23:27:20
User entered '2 Nov 2020'	(b) (4)	02 Nov 2020 23:27:20
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Nov 2020 23:25:17
User entered '2 Nov 2020'	Ethan Shotton (b) (4)	02 Nov 2020 23:25:17
	(b) (4)	02 Nov 2020 23:25:17

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty; reason for change Data Entry Error	(b) (4)	04 Nov 2020 20:33:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	Eileen Euperio (b) (4)	04 Nov 2020 20:33:16
	(b) (4)	
	Ethan Shotton (b) (4)	02 Nov 2020 23:25:17
	(b) (4)	

US3342343

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'CONTACT NOT MADE DUE TO CONVALESCENT PERIOD. SAFETY CALL DAY 15 WAS SKIPPED.' reason for change: Data Entry Error	Ethan Shotton (b) (4)	04 Nov 2020 20:22:39
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).		02 Nov 2020 23:27:20
User entered 'Contact not made due to convalescent period' reason for change: Data Entry Error	Ethan Shotton (b) (4)	02 Nov 2020 23:27:20
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	02 Nov 2020 23:25:17
User entered empty.	Ethan Shotton (b) (4)	02 Nov 2020 23:25:17

US3342343

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Ethan Shotton (b) (4)	02 Nov 2020 23:28:20

US3342343

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:20:31
User entered '1'	System	02 Nov 2020 23:28:20

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:16
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:35

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:16
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '2 Nov 2020'	(b) (4) Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:35

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:16
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:35

US3342343

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:16
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:35

US3342343

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:16
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:24:41

US3342343

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:16
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:49
User entered '1'	System	04 Nov 2020 20:24:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:10:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '9 Nov 2020'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:10:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[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 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:10:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'VISIT2'	System	09 Nov 2020 21:10:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '9 Nov 2020'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '09:33'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered '9 Nov 2020 09:33'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '99.0' F	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Oral (Oral)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '58'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'bpm'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '14'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'breaths/min'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '123'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'mmHg'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '82'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'mmHg'	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:11:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '9 Nov 2020'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:11:41

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

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)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	09 Nov 2020 21:12:18

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	12 Nov 2020 21:03:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '09 Nov 2020'	(b) (4) Andrew Bell (b) (4)	12 Nov 2020 21:03:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '10:43'	(b) (4) Andrew Bell (b) (4)	12 Nov 2020 21:03:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered '09 Nov 2020 10:43'	System	12 Nov 2020 21:03:43

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '09 Nov 2020'	(b) (4) Andrew Bell (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '10:45'	(b) (4) Andrew Bell (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered '09 Nov 2020 10:45'	System	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) Andrew Bell (b) (4)	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered empty.	System	12 Nov 2020 21:04:03

US3342343

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:12:27

US3342343

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'I'	System	09 Nov 2020 21:12:27

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	16 Nov 2020 20:47:10

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '16 Nov 2020'	Ethan Shotton (b) (4)	16 Nov 2020 20:47:10

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	16 Nov 2020 20:47:10

US3342343

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	Ethan Shotton (b) (4)	16 Nov 2020 20:47:10

US3342343

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	16 Nov 2020 20:47:14

US3342343

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'I'	System	16 Nov 2020 20:47:14

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:43:57

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:43:57

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:43:57

US3342343

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:43:57

US3342343

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:44:02

US3342343

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'I'	System	23 Nov 2020 22:44:02

US3342343

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:27:14

US3342343

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:27:14

US3342343

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:27:14

US3342343

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:27:14

US3342343

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:27:18

US3342343

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'I'	System	30 Nov 2020 15:27:18

US3342343

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD Central lab has sample dated 04DEC2020 reported under Visit 3 Day 57 visit, however the data is missing in EDC. Please review if the sample has been collected then update EDC or PPD portal. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 12:00:01
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD Central lab has sample dated 04DEC2020 reported under Visit 3 Day 57 visit, however the data is missing in EDC. Please review if the sample has been collected then update EDC or PPD portal. Else clarify, thank you.' answered with 'this has been updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	19 Jan 2021 22:37:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD Central lab has sample dated 04DEC2020 reported under Visit 3 Day 57 visit, however the data is missing in EDC. Please review if the sample has been collected then update EDC or PPD portal. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:44:48
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	04 Dec 2020 16:45:55

US3342343

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '04 Dec 2020'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:45:55

US3342343

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[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 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Clinic (Clinic)'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:45:55

US3342343

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'VISIT3'	System	04 Dec 2020 16:45:55

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '04 Dec 2020'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '10:14'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered '04 Dec 2020 10:14'	System	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '98.5' F	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Oral (Oral)'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '55'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'bpm'	System	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '14'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'breaths/min'	System	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '131'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'mmHg'	System	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '84'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered 'mmHg'	System	04 Dec 2020 16:46:26

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38

US3342343

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38

US3342343

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'No (N)'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:35

US3342343

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:35

US3342343

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:18:34

US3342343

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:18:34

US3342343

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered '10:35'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:18:34

US3342343

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered '4 Dec 2020 10:35'	System	23 Dec 2020 20:18:34

US3342343

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:06:26
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	04 Dec 2020 16:46:44

US3342343

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered '1'	System	04 Dec 2020 16:46:44

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2020-12-11T15:58:14', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '4391c6b6-ee52-41c1-817a-791694f776ab'	System	11 Dec 2020 21:58:30
User entered 'No (N)'	System	11 Dec 2020 21:58:30

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2020-12-11T15:58:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '4391c6b6-ee52-41c1-817a-791694f776ab'	System	11 Dec 2020 21:58:30
User entered 'No (N)'	System	11 Dec 2020 21:58:30

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-12-11T15:58:29', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '4391c6b6-ee52-41c1-817a-791694f776ab'	System	11 Dec 2020 21:58:30
User entered '11 Dec 2020 15:58:29'	System	11 Dec 2020 21:58:30

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2020-12-20T12:40:19', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '135f1df3-95f8-4624-80a1-b6ba05ddb1cc'	System	20 Dec 2020 18:40:38
User entered 'No (N)'	System	20 Dec 2020 18:40:38

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2020-12-20T12:40:31', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '135f1df3-95f8-4624-80a1-b6ba05ddb1cc'	System	20 Dec 2020 18:40:38
User entered 'No (N)'	System	20 Dec 2020 18:40:38

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-12-20T12:40:35', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '135f1df3-95f8-4624-80a1-b6ba05ddb1cc'	System	20 Dec 2020 18:40:38
User entered '20 Dec 2020 12:40:35'	System	20 Dec 2020 18:40:38

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2020-12-26T18:18:29', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '39112aa3-7824-4edc-9fda-6b020f0f2783'	System	27 Dec 2020 00:19:08
User entered 'Yes (Y)'	System	27 Dec 2020 00:19:08

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2020-12-26T18:18:41', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '39112aa3-7824-4edc-9fda-6b020f0f2783'	System	27 Dec 2020 00:19:08
User entered 'No (N)'	System	27 Dec 2020 00:19:08

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 (1858609a30306a15)', Time: '2020-12-26T18:18:49', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '39112aa3-7824-4edc-9fda-6b020f0f2783'	System	27 Dec 2020 00:19:08
User entered 'No (N)'	System	27 Dec 2020 00:19:08

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 (1858609a30306a15)', Time: '2020-12-26T18:19:01', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '39112aa3-7824-4edc-9fda-6b020f0f2783'	System	27 Dec 2020 00:19:08
User entered 'No (N)'	System	27 Dec 2020 00:19:08

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2020-12-26T18:19:06', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '39112aa3-7824-4edc-9fda-6b020f0f2783'	System	27 Dec 2020 00:19:08
User entered '26 Dec 2020 18:19:06'	System	27 Dec 2020 00:19:08

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-01-01T22:04:14', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c76d0e82-0f1c-4075-b117-f82821e34609'	System	02 Jan 2021 04:04:23
User entered 'No (N)'	System	02 Jan 2021 04:04:23

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-01-01T22:04:18', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c76d0e82-0f1c-4075-b117-f82821e34609'	System	02 Jan 2021 04:04:23
User entered 'No (N)'	System	02 Jan 2021 04:04:23

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-01-01T22:04:21', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'c76d0e82-0f1c-4075-b117-f82821e34609'	System	02 Jan 2021 04:04:23
User entered '01 Jan 2021 22:04:21'	System	02 Jan 2021 04:04:23

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-01-14T05:13:37', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5b60be2d-6a9f-4438-9f17-450d8857dec9'	System	14 Jan 2021 11:13:49
User entered 'No (N)'	System	14 Jan 2021 11:13:49

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-01-14T05:13:43', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5b60be2d-6a9f-4438-9f17-450d8857dec9'	System	14 Jan 2021 11:13:49
User entered 'No (N)'	System	14 Jan 2021 11:13:49

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-01-14T05:13:47', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5b60be2d-6a9f-4438-9f17-450d8857dec9' User entered '14 Jan 2021 05:13:47'	System	14 Jan 2021 11:13:49
	System	14 Jan 2021 11:13:49

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-01-20T19:06:04', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '69e32ac3-0152-452e-a7e8-e2c0e11fe4a3'	System	21 Jan 2021 01:06:13
User entered 'No (N)'	System	21 Jan 2021 01:06:13

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-01-20T19:06:07', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '69e32ac3-0152-452e-a7e8-e2c0e11fe4a3'	System	21 Jan 2021 01:06:13
User entered 'No (N)'	System	21 Jan 2021 01:06:13

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-01-20T19:06:11', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '69e32ac3-0152-452e-a7e8-e2c0e11fe4a3'	System	21 Jan 2021 01:06:13
User entered '20 Jan 2021 19:06:11'	System	21 Jan 2021 01:06:13

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-01-27T00:01:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f021e9f7-04ce-4334-bc88-df20d7449b38'	System	27 Jan 2021 06:01:40
User entered 'No (N)'	System	27 Jan 2021 06:01:40

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-01-27T00:01:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f021e9f7-04ce-4334-bc88-df20d7449b38'	System	27 Jan 2021 06:01:40
User entered 'No (N)'	System	27 Jan 2021 06:01:40

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-01-27T00:01:27', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'f021e9f7-04ce-4334-bc88-df20d7449b38'	System	27 Jan 2021 06:01:40
User entered '27 Jan 2021 00:01:27'	System	27 Jan 2021 06:01:40

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-02-04T11:02:20', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '06ed9735-df91-9a57-1e13651eb5ad'	System	08 Feb 2021 20:42:52
User entered 'No (N)'	System	08 Feb 2021 20:42:52

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-02-04T11:02:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '06ed9735-df91-9a57-1e13651eb5ad'	System	08 Feb 2021 20:42:52
User entered 'No (N)'	System	08 Feb 2021 20:42:52

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-02-04T11:02:24', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '06ed9735-df91-9a57-1e13651eb5ad'	System	08 Feb 2021 20:42:52
User entered '04 Feb 2021 11:02:24'	System	08 Feb 2021 20:42:52

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-02-11T15:46:22', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd90eb49e-f843-481a-b5c1-c0d578fc69e5'	System	11 Feb 2021 21:46:59
User entered 'Yes (Y)'	System	11 Feb 2021 21:46:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-02-11T15:46:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd90eb49e-f843-481a-b5c1-c0d578fc69e5'	System	11 Feb 2021 21:46:59
User entered 'No (N)'	System	11 Feb 2021 21:46:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-02-11T15:46:48', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd90eb49e-f843-481a-b5c1-c0d578fc69e5'	System	11 Feb 2021 21:46:59
User entered 'No (N)'	System	11 Feb 2021 21:46:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-02-11T15:46:53', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd90eb49e-f843-481a-b5c1-c0d578fc69e5'	System	11 Feb 2021 21:46:59
User entered 'No (N)'	System	11 Feb 2021 21:46:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-02-11T15:46:56', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd90eb49e-f843-481a-b5c1-c0d578fc69e5'	System	11 Feb 2021 21:46:59
User entered '11 Feb 2021 15:46:56'	System	11 Feb 2021 21:46:59

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-02-19T22:49:13', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '50941d9f-cdef-4e9d-83ee-e5c8aa26d19a'	System	20 Feb 2021 04:50:48
User entered 'Yes (Y)'	System	20 Feb 2021 04:50:48

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-02-19T22:49:17', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '50941d9f-cdef-4e9d-83ee-e5c8aa26d19a'	System	20 Feb 2021 04:50:48
User entered 'No (N)'	System	20 Feb 2021 04:50:48

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 (1858609a30306a15)', Time: '2021-02-19T22:49:26', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '50941d9f-cdef-4e9d-83ee-e5c8aa26d19a'	System	20 Feb 2021 04:50:48
User entered 'No (N)'	System	20 Feb 2021 04:50:48

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

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 (1858609a30306a15)', Time: '2021-02-19T22:49:32', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '50941d9f-cdef-4e9d-83ee-e5c8aa26d19a'	System	20 Feb 2021 04:50:48
User entered 'No (N)'	System	20 Feb 2021 04:50:48

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-02-19T22:49:36', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '50941d9f-cdef-4e9d-83ee-e5c8aa26d19a'	System	20 Feb 2021 04:50:48
User entered '19 Feb 2021 22:49:36'	System	20 Feb 2021 04:50:48

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-03-14T19:07:20-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'e370f3d9-a50b-4e6b-8ef1-716970d027d3'	System	15 Mar 2021 00:07:31
User entered 'No (N)'	System	15 Mar 2021 00:07:31

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-03-14T19:07:25-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'e370f3d9-a50b-4e6b-8ef1-716970d027d3'	System	15 Mar 2021 00:07:31
User entered 'No (N)'	System	15 Mar 2021 00:07:31

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-03-14T19:07:28-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'e370f3d9-a50b-4e6b-8ef1-716970d027d3'	System	15 Mar 2021 00:07:31
User entered '14 Mar 2021 19:07:28'	System	15 Mar 2021 00:07:31

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-03-17T07:59:13-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5c334a4c-218d-4e8c-aa3c-e8a00b720222'	System	17 Mar 2021 12:59:23
User entered 'No (N)'	System	17 Mar 2021 12:59:23

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-03-17T07:59:17-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5c334a4c-218d-4e8c-aa3c-e8a00b720222'	System	17 Mar 2021 12:59:23
User entered 'No (N)'	System	17 Mar 2021 12:59:23

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-03-17T07:59:20-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: '5c334a4c-218d-4e8c-aa3c-e8a00b720222'	System	17 Mar 2021 12:59:23
User entered '17 Mar 2021 07:59:20'	System	17 Mar 2021 12:59:23

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-04-09T17:39:07-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd2087541-db93-4708-9109-4d8cb7fa3d6b'	System	09 Apr 2021 22:39:19
User entered 'No (N)'	System	09 Apr 2021 22:39:19

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-04-09T17:39:11-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd2087541-db93-4708-9109-4d8cb7fa3d6b'	System	09 Apr 2021 22:39:19
User entered 'No (N)'	System	09 Apr 2021 22:39:19

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-04-09T17:39:17-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'd2087541-db93-4708-9109-4d8cb7fa3d6b'	System	09 Apr 2021 22:39:19
User entered '09 Apr 2021 17:39:17'	System	09 Apr 2021 22:39:19

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[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 (1858609a30306a15)', Time: '2021-04-21T14:00:45-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b1a85fe8-bd7c-4d71-8091-aa0996f95923'	System	21 Apr 2021 19:01:21
User entered 'No (N)'	System	21 Apr 2021 19:01:21

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

Have you been exposed to someone with 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 (1858609a30306a15)', Time: '2021-04-21T14:01:08-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b1a85fe8-bd7c-4d71-8091-aa0996f95923'	System	21 Apr 2021 19:01:21
User entered 'No (N)'	System	21 Apr 2021 19:01:21

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-04-21T14:01:12-05:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'b1a85fe8-bd7c-4d71-8091-aa0996f95923'	System	21 Apr 2021 19:01:21
User entered '21 Apr 2021 14:01:12'	System	21 Apr 2021 19:01:21

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:53:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '07 Dec 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '11 Dec 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '14 Dec 2022 00:01'	System	20 Nov 2020 11:53:32

US3342343

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:53:32
Amendment Manager: User entered '18 Dec 2022 23:59'	System	20 Nov 2020 11:53:32

US3342343

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:08:26

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)	25 Apr 2021 02:37:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-03-08T16:13:52-06:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'dc378d2e-5e26-4443-bc25-2d2f6a7ac93b'	System	08 Mar 2021 22:14:06
User entered 'No (N)'	System	08 Mar 2021 22:14:06

US3342343

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:08:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1858609a30306a15)', Time: '2021-03-08T16:14:03-06:00', User OID: 'PatientReportedOutcome (US3342343)', ODM File OID: 'dc378d2e-5e26-4443-bc25-2d2f6a7ac93b'	System	08 Mar 2021 22:14:06
User entered '08 Mar 2021 16:14:03'	System	08 Mar 2021 22:14:06

US3342343

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:23:48

US3342343

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:23:48

US3342343

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:23:48

US3342343

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:23:48

US3342343

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:23:51

US3342343

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:38
User entered '1'	System	04 Jan 2021 19:23:51

US3342343

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:04:54

US3342343

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:04:54

US3342343

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:04:54

US3342343

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:04:54

US3342343

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:04:59

US3342343

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User entered '1'	System	04 Feb 2021 18:04:59

US3342343

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:48:13

US3342343

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '08 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:48:13

US3342343

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:48:13

US3342343

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:48:13

US3342343

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:48:16

US3342343

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:02
User entered '1'	System	08 Mar 2021 16:48:16

US3342343

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	07 Apr 2021 13:37:25
	(b) (4)	

US3342343

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
	(b) (4)	
User entered '05 Apr 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4)	07 Apr 2021 13:37:36
	(b) (4)	
User entered '5 Apr 2021'	Ethan Shotton (b) (4)	07 Apr 2021 13:37:25
	(b) (4)	

US3342343

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ethan Shotton (b) (4)	07 Apr 2021 13:37:25
	(b) (4)	

US3342343

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered empty.	(b) (4) Ethan Shotton (b) (4)	07 Apr 2021 13:37:25
	(b) (4)	

US3342343

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	07 Apr 2021 13:37:30
	(b) (4)	

US3342343

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 13:37:30

US3342343

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	27 Apr 2021 19:51:03
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered '27 Apr 2021'	Ethan Shotton (b) (4)	27 Apr 2021 19:51:03
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'Clinic (Clinic)'	Ethan Shotton (b) (4)	27 Apr 2021 19:51:03
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	27 Apr 2021 19:51:03

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered 'Yes (Y)'	(b) (4) Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered '27 Apr 2021'	(b) (4) Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered '13:29'	(b) (4) Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 13:29'	System	27 Apr 2021 19:51:40

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered '97.9' F	Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered 'Oral (Oral)'	(b) (4) Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered '67'	(b) (4) Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Apr 2021 19:51:40

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered '14'	(b) (4) Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Apr 2021 19:51:40

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered '135'	(b) (4) Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Apr 2021 19:51:40

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered '92'	Ethan Shotton (b) (4)	27 Apr 2021 19:51:40
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Apr 2021 19:51:40

US3342343

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	27 Apr 2021 19:51:45
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	27 Apr 2021 19:51:45
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:06
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Apr 2021 14:02:09
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:06
	(b) (4)	
User entered '27 Apr 2021'	Ethan Shotton (b) (4)	29 Apr 2021 14:02:09
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:06
	(b) (4)	
User entered '14:02'	Ethan Shotton (b) (4)	29 Apr 2021 14:02:09
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 14:02'	System	29 Apr 2021 14:02:09

US3342343

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered 'Yes (Y)'	(b) (4) Ethan Shotton (b) (4)	27 Apr 2021 19:51:50
	(b) (4)	

US3342343

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 19:51:50

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:37
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 11-Mar-2021 for Illness Visit Day 1; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Paul Pickrell (b) (4)	09 Apr 2021 12:59:42 29 Mar 2021 22:12:10
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 11-Mar-2021 for Illness Visit Day 1; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you' answered with 'please clarify as this data is entered under covid diagnostic test eCRF' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	18 Mar 2021 20:59:46
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 11-Mar-2021 for Illness Visit Day 1; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you' (Site from DM). User entered '11 Mar 2021'	(b) (4), (b) (6) Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 11:00:38 11 Mar 2021 21:35:24

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:37
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '13:30'	Ethan Shotton (b) (4)	11 Mar 2021 21:35:24

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:37
User entered '11 Mar 2021 13:30'	System	11 Mar 2021 21:35:24

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:37
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Ethan Shotton (b) (4)	11 Mar 2021 21:35:24

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:37
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	11 Mar 2021 21:35:24

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 1 (Day 1)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '07 Mar 2021'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:39:27

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 2 (Day 2)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '08 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	11 Mar 2021 21:41:18
User entered missing code ND - Not Done.	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20
	(b) (4)	

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Mar 2021 21:41:18
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20
	(b) (4)	

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:40:20

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 3 (Day 3)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '09 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	11 Mar 2021 21:41:18

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:18

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 4 (Day 4)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '10 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	11 Mar 2021 21:41:57

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:41:57

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 5 (Day 5)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '100'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '99.0' F	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	Ethan Shotton (b) (4)	11 Mar 2021 21:42:44

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 6 (Day 6)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '12 Mar 2021'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '97.6' F	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Mar 2021 23:10:19

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 7 (Day 7)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '13 Mar 2021'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.9' F	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:31

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Folder: Covid-19 Assessment 11 Mar 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 8 (Day 8)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14 Mar 2021'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '99'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	15 Mar 2021 01:29:58

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '97.9' F	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Mar 2021 01:29:58

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Folder: Covid-19 Assessment 11 Mar 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 9 (Day 9)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '15 Mar 2021'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '100'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.0' F	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

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Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 13:39:12

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Folder: Covid-19 Assessment 11 Mar 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 10 (Day 10)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '16 Mar 2021'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '99'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	16 Mar 2021 20:34:31

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Folder: Covid-19 Assessment 11 Mar 2021

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96.8' F	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Mar 2021 20:34:31

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 11 (Day 11)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '17 Mar 2021'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '99'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User entered '%'	System	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.9' F	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:43
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Mar 2021 20:14:36

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11 Mar 2021'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11 Mar 2021'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:49
User entered '0'	System	18 Mar 2021 14:45:13

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:16
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '22 Oct 2020'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:16
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11:35'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:16
User entered '22 Oct 2020 11:35'	System	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:16
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:26

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:16
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:07:05

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 2 (Day 2)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
Signature has been broken.	(b) (4) Olivia Hapanowicz (b) (4)	23 Apr 2021 13:58:45
User signature succeeded.	(b) (4) Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '22 Oct 2020'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 16:24:12
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User entered '%'	System	05 Nov 2020 16:24:12
User entered empty.	System	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	05 Nov 2020 16:24:12
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per CDM: Some assessments are not done for loglines 2-8. Please consider adding missing data or if there is no data available then please consider selecting "Not Done". Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:15:35
Query 'Per CDM: Some assessments are not done for loglines 2-8. Please consider adding missing data or if there is no data available then please consider selecting "Not Done". Thank you' answered with 'data entered' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:29:00
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User opened query 'Per CDM: Some assessments are not done for loglines 2-8. Please consider adding missing data or if there is no data available then please consider selecting "Not Done". Thank you' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:40:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:24:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 3 (Day 3)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '23 Oct 2020'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 16:24:12
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User entered '%'	System	05 Nov 2020 16:24:12
User entered empty.	System	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	05 Nov 2020 16:24:12
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Form: Symptom Log (3)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:25:40
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 4 (Day 4)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '24 Oct 2020'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 16:26:15
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34
	(b) (4)	

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Form: Symptom Log (4)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User entered '%'	System	05 Nov 2020 16:26:15
User entered empty.	System	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	05 Nov 2020 16:26:15
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:09
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 5 (Day 5)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '25 Oct 2020'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 16:26:15
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User entered '%'	System	05 Nov 2020 16:26:15
User entered empty.	System	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	05 Nov 2020 16:26:15
User entered empty.	Eileen Euperio (b) (4)	27 Oct 2020 15:29:34
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:26:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 6 (Day 6)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '26 Oct 2020'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User entered '%'	System	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96.4' F	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Mild (Mild)'	(b) (4) Eileen Euperio (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:27:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 15:29:34

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 7 (Day 7)'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '27 Oct 2020'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96'	(b) (4) Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User entered '%'	System	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.1' F	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'None (None)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 16:28:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 8 (Day 8)'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '28 Oct 2020'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User entered '%'	System	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.0' F	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Day 9 (Day 9)'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '29 Oct 2020'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '100'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User entered '%'	System	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '96.0' F	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:21
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:26:15

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per GCL Lab recon: Swab: Sample collection date 23-OCT-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in GCL. Kindly confirm if swab sample was collected on 23-OCT-2020 for Covid-19 Assessment visit to be updated in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:38:35
Query 'Per GCL Lab recon: Swab: Sample collection date 23-OCT-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in GCL. Kindly confirm if swab sample was collected on 23-OCT-2020 for Covid-19 Assessment visit to be updated in GCL records.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	25 Nov 2020 18:57:18
User entered '22 Oct 2020' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	25 Nov 2020 18:56:51
User opened query 'Per GCL Lab recon: Swab: Sample collection date 23-OCT-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in GCL. Kindly confirm if swab sample was collected on 23-OCT-2020 for Covid-19 Assessment visit to be updated in GCL records.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 04:36:47
User entered '23 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 18:57:08
User entered '23 Oct 2020'	Darrell O'Brien (b) (4)	25 Nov 2020 18:57:08
	(b) (4)	
	Eileen Euperio (b) (4)	05 Nov 2020 16:54:09
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Eileen Euperio (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:54:09
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:26

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:27
User entered '0'	System	05 Nov 2020 16:54:09

US3342343

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:08:26

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:25:32
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:54:23

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the same is reported with date 24OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 05:30:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the same is reported with date 24OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	25 Nov 2020 18:54:35
User entered '24 Oct 2020' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	25 Nov 2020 18:54:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the same is reported with date 24OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:48:12
User entered '23 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 25OCT2020 is recorded under Illness visit in EDC, however day 5 is reported under Illness visit with date 24OCT2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 05:32:27
Query 'Per GCL Lab Recon: Saliva: Sample dated 25OCT2020 is recorded under Illness visit in EDC, however day 5 is reported under Illness visit with date 24OCT2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you. ' answered with 'DAY 5 26OCT2020. WILL UPDATE IN PRECLARUS' (Site from DM).	Stefanie Mott (b) (4)	22 Mar 2021 16:52:38
User entered '26 Oct 2020' reason for change: Data Entry Error	Stefanie Mott (b) (4)	22 Mar 2021 16:52:22
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 25OCT2020 is recorded under Illness visit in EDC, however day 5 is reported under Illness visit with date 24OCT2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:45:58
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25,29OCT2020 is recorded under Illness Visit Day 5,9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 11:48:51

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25,29OCT2020 is recorded under Illness Visit Day 5,9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Day 5 collected and scanned as received at site on 24OCT2020. Date of receipt scanned in error rather than date of saliva collection.' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	20 Jan 2021 23:54:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25,29OCT2020 is recorded under Illness Visit Day 5,9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:22:59
User entered '25 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is recorded under Illness Visit Day 7 visit in EDC, however the same is reported with date 28OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 05:30:19
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is recorded under Illness Visit Day 7 visit in EDC, however the same is reported with date 28OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	25 Nov 2020 18:55:07
User entered '28 Oct 2020' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	25 Nov 2020 18:55:02
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is recorded under Illness Visit Day 7 visit in EDC, however the same is reported with date 28OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:54:37
User entered '27 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	22 Mar 2021 16:51:29
	(b) (4)	
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 05:32:36
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PT DID NOT COLLECT SALIVA DAY 9. UPDATED IN EDC. ' (Site from DM).	Stefanie Mott (b) (4)	22 Mar 2021 16:51:47
User entered empty; reason for change Data Entry Error	Stefanie Mott (b) (4)	22 Mar 2021 16:51:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:44:54
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25,29OCT2020 is recorded under Illness Visit Day 5,9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 15:15:41

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25,29OCT2020 is recorded under Illness Visit Day 5,9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). User entered '29 Oct 2020'	(b) (4), (b) (6) [REDACTED]	21 Jan 2021 11:49:36
	Eileen Euperio (b) (4) [REDACTED]	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Eileen Euperio (b) (4) (b) (4)	05 Nov 2020 16:22:24

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Eileen Euperio (b) (4)	05 Nov 2020 16:22:24
	(b) (4)	

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '13 Mar 2021'	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '15 Mar 2021'	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: sample dated 17mar2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:18:28
Query 'Per GCL LAB reconciliation: Saliva: sample dated 17mar2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.'	Olivia Hapanowicz (b) (4)	26 Mar 2021 21:08:54
answered with 'PPD updated' (Site from DM).	(b) (4)	
User opened query 'Per GCL LAB reconciliation: Saliva: sample dated 17mar2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 17:01:59
User accepted default value 'Day 7 (Day 7)'	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '17 Mar 2021'	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41
	[REDACTED]	
	[REDACTED]	

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41
	[REDACTED]	
	[REDACTED]	

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:45:41

US3342343

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	18 Mar 2021 14:45:41
	[REDACTED]	
	[REDACTED]	

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 22 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 07:50:16
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 22 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	25 Nov 2020 18:52:56
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 22 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:17:12
User entered '22 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Clinic (Clinic)'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'SICKD1'	System	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '22 Oct 2020'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11:53'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered '22 Oct 2020 11:53'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '166.5' cm	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13
DataPoint set to visible.	(b) (4) System	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '85.8' kg	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13
DataPoint set to visible.	(b) (4) System	22 Oct 2020 23:03:21

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.2' F	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Oral (Oral)'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '54'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'bpm'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '12'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'breaths/min'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '131'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'mmHg'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '85'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'mmHg'	System	22 Oct 2020 23:04:13

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08

US3342343

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:27

US3342343

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '22 Oct 2020'	(b) (4) Darrell O'Brien (b) (4)	22 Oct 2020 23:04:27

US3342343

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:26

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	25 Nov 2020 18:42:45

US3342343

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '22 Oct 2020'	(b) (4) Darrell O'Brien (b) (4)	25 Nov 2020 18:42:45

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	11 Mar 2021 21:33:39

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 21:33:39

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Clinic (Clinic)'	Ethan Shotton (b) (4)	11 Mar 2021 21:33:39

US3342343

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'SICKD1'	System	11 Mar 2021 21:33:39

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '13:57'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered '11 Mar 2021 13:57'	System	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:34:26
DataPoint set to visible.	(b) (4) System	11 Mar 2021 21:33:39

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:34:26
DataPoint set to visible.	(b) (4) System	11 Mar 2021 21:33:39

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '99.0' F	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Oral (Oral)'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '79'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'bpm'	System	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '16'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'breaths/min'	System	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '124'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'mmHg'	System	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '86'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User entered 'mmHg'	System	11 Mar 2021 21:34:26

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08

US3342343

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08

US3342343

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:31

US3342343

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4) System	11 Mar 2021 21:34:37
User entered '11 Mar 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 21:34:37
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	11 Mar 2021 21:34:31
User entered empty.	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 21:34:31

US3342343

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:26

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	11 Mar 2021 21:34:41

US3342343

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User closed query 'Per GCL Lab Recon: SARS-COV2: Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? was given "Yes". However, date of collection is missing. Please review and update the collection date in the EDC. Please review if this sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:09:59
Query 'Per GCL Lab Recon: SARS-COV2: Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? was given "Yes". However, date of collection is missing. Please review and update the collection date in the EDC. Please review if this sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'date entered; accession number 1F636013711. can confirm sample has been shipped.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	06 Apr 2021 13:12:12
Signature has been broken.	Olivia Hapanowicz (b) (4) (b) (4)	06 Apr 2021 13:11:08
User entered '11 Mar 2021' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	06 Apr 2021 13:11:08
User opened query 'Per GCL Lab Recon: SARS-COV2: Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? was given "Yes". However, date of collection is missing. Please review and update the collection date in the EDC. Please review if this sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:35:22
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10

US3342343

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 21:34:41

US3342343

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:07:23

US3342343

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:07:23

US3342343

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:07:23

US3342343

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 21:07:23

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:08:04

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:18:44

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:11:13
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'PATIENT WAS UNBLINDED PRIOR TO RECEIVING PLACEBO DOSE 2' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 21:08:47
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	14 Jan 2021 21:08:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:08:04

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:18:44

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:08:04

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:08:04

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 15:51:51
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 21:08:04

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 15:51:51
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 21:10:09
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:08:04

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:08:04

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '1'	System	14 Jan 2021 21:10:09
User entered empty.	System	14 Jan 2021 21:08:04

US3342343

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '1'	System	14 Jan 2021 21:10:09
User entered empty.	System	14 Jan 2021 21:08:04

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered empty.	System	14 Jan 2021 21:13:48
DataPoint set to visible.	System	14 Jan 2021 21:10:09

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered empty.	System	14 Jan 2021 21:13:48
DataPoint set to visible.	System	14 Jan 2021 21:10:09

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '13:20'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '14 Jan 2021 13:20'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '098.6' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '077'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'bpm'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '015'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'breaths/min'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '151'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '097'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered empty.	System	14 Jan 2021 21:13:48
DataPoint set to visible.	System	14 Jan 2021 21:10:09

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14:35'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '14 Jan 2021 14:35'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '098.6' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '056'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'bpm'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '016'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'breaths/min'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '137'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '087'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:48

US3342343

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	14 Jan 2021 21:13:48

US3342343

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:54

US3342343

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:13:54

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:14:50

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:19
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:14:50

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:19
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:14:50

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mRNA-1273'	System	14 Jan 2021 21:14:50
DataPoint set to visible.	System	14 Jan 2021 21:10:09

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:19
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:14:50

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:19
User entered '13:58'	(b) (4), (b) (6)	14 Jan 2021 21:14:50

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '14 Jan 2021 13:58'	System	14 Jan 2021 21:14:50

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:48:19
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Jan 2021 21:14:50

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:48:19
User entered 'ONCE'	System	14 Jan 2021 21:14:50

US3342343

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 21:14:50

US3342343

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	15 Jan 2021 22:18:22

US3342343

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 14Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 14Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'sample was received, req number 1F605174425' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:01:11
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 14Jan2021. Please provide accession number and tracking or clarify. Thank you.'	Olivia Hapanowicz (b) (4)	08 Feb 2021 19:14:57
User entered '14 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 18:41:44
	Eileen Euperio (b) (4)	15 Jan 2021 22:18:22

US3342343

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '13:48'	(b) (4) Eileen Euperio (b) (4) (b) (4)	15 Jan 2021 22:18:22

US3342343

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '14 Jan 2021 13:48'	System	15 Jan 2021 22:18:22

US3342343

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	15 Jan 2021 22:18:10

US3342343

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	15 Jan 2021 22:18:10

US3342343

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '13:50'	(b) (4) Eileen Euperio (b) (4)	15 Jan 2021 22:18:10
	(b) (4)	

US3342343

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:26

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '14 Jan 2021 13:50'	System	15 Jan 2021 22:18:10

US3342343

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

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:14:54

US3342343

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

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '1'	System	14 Jan 2021 21:14:54

US3342343

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 16:16:05

US3342343

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '21 Jan 2021'	Ethan Shotton (b) (4)	21 Jan 2021 16:16:05

US3342343

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	21 Jan 2021 16:16:05

US3342343

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:16:05

US3342343

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 16:20:36

US3342343

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '1'	System	21 Jan 2021 16:20:36

US3342343

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '1'	System	21 Jan 2021 16:20:36
DataPoint set to visible.	System	21 Jan 2021 16:20:36

US3342343

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:17

US3342343

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Please note that the sample dated 08FEB2021 is present under OL-D29 Visit in PPD GCL and the same sample data is not entered in EDC. Please update the sample date in EDC under appropriate Visit, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:11:13
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Please note that the sample dated 08FEB2021 is present under OL-D29 Visit in PPD GCL and the same sample data is not entered in EDC. Please update the sample date in EDC under appropriate Visit, else clarify.' answered with 'lab collected in error, protocol deviation logged. data entered as unscheduled 08Feb2021 because unable to enter it under OL-D29 folder.' (Site from DM).	Olivia Hapanowicz (b) (4)	06 Apr 2021 13:16:25
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Please note that the sample dated 08FEB2021 is present under OL-D29 Visit in PPD GCL and the same sample data is not entered in EDC. Please update the sample date in EDC under appropriate Visit, else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 11:46:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:17

US3342343

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:17

US3342343

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'OLD29'	System	08 Feb 2021 22:28:17

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Feb 2021 22:28:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Feb 2021 22:28:05
User entered '14:44' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 22:28:05
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 22:26:41
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '08 Feb 2021 14:44'	System	08 Feb 2021 22:28:05
User entered empty.	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Feb 2021 22:28:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Feb 2021 22:28:05
User entered '98.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 22:28:05
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 22:26:41
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '68' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:05
User entered '55'	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'bpm'	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '17' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:05
User entered '14'	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'breaths/min'	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '145' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:05
User entered '138'	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '85' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:05
User entered '89'	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '15:53'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '08 Feb 2021 15:53'	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Feb 2021 22:28:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Feb 2021 22:28:05
User entered '55' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 22:28:05
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 22:26:41
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'bpm'	System	08 Feb 2021 22:28:05
User entered empty.	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Feb 2021 22:28:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Feb 2021 22:28:05
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 22:28:05
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 22:26:41
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'breaths/min'	System	08 Feb 2021 22:28:05
User entered empty.	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Feb 2021 22:28:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Feb 2021 22:28:05
User entered '138' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 22:28:05
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 22:26:41
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	08 Feb 2021 22:28:05
User entered empty.	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Feb 2021 22:28:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Feb 2021 22:28:05
User entered '89' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 22:28:05
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 22:26:41
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	08 Feb 2021 22:28:05
User entered empty.	System	08 Feb 2021 22:26:41

US3342343

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:24

US3342343

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:28:24

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mRNA-1273'	System	08 Feb 2021 22:26:01
DataPoint set to visible.	System	21 Jan 2021 16:20:36

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '15:23'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '08 Feb 2021 15:23'	System	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'ONCE'	System	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 22:26:01

US3342343

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:26:06

US3342343

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '1'	System	08 Feb 2021 22:26:06

US3342343

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:29:38

US3342343

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:07
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Due to widespread power outages due to incimate weather, office was closed and safety calls were unable to be completed. See note to file. ' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 14:31:37
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Feb 2021 14:29:38
User entered '21 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 14:29:38

US3342343

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:29:38

US3342343

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:29:38

US3342343

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:09:58

US3342343

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'I'	System	11 Mar 2021 21:09:58

US3342343

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:10:09

US3342343

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:10:09

US3342343

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:10:09

US3342343

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'OLD57'	System	11 Mar 2021 21:10:09

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '13:57'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '11 Mar 2021 13:57'	System	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '79'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'bpm'	System	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'breaths/min'	System	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '124'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '86'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered 'mmHg'	System	11 Mar 2021 21:12:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12

US3342343

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12

US3342343

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User closed query 'Per CDM: Please be aware that Illness Visit Day 1 and OL-D57 took place exactly the same day. However, "Physical Examination" was done at the Illness Visit, but on OL-D57 it was not done. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:22:01
Query 'Per CDM: Please be aware that Illness Visit Day 1 and OL-D57 took place exactly the same day. However, "Physical Examination" was done at the Illness Visit, but on OL-D57 it was not done. Please clarify why there is a difference or update the field. Thank you!' answered with 'this has been corrected' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 16:35:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 16:34:37
User opened query 'Per CDM: Please be aware that Illness Visit Day 1 and OL-D57 took place exactly the same day. However, "Physical Examination" was done at the Illness Visit, but on OL-D57 it was not done. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:19:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:12:20

US3342343

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '11 Mar 2021' reason for change: Data Entry Error	(b) (4)	01 Apr 2021 16:34:37
User entered empty.	Olivia Hapanowicz (b) (4)	11 Mar 2021 21:12:20
	(b) (4), (b) (6)	

US3342343

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	16 Mar 2021 12:20:43

US3342343

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	16 Mar 2021 12:20:55
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	16 Mar 2021 12:20:55
User entered '11 Mar 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4)	16 Mar 2021 12:20:55
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	16 Mar 2021 12:20:43
User entered '12 Mar 2021'	Ethan Shotton (b) (4)	16 Mar 2021 12:20:43

US3342343

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '14:22'	Ethan Shotton (b) (4)	16 Mar 2021 12:20:43

US3342343

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:14:12
User entered '11 Mar 2021 14:22'	System	16 Mar 2021 12:20:55
User entered '12 Mar 2021 14:22'	System	16 Mar 2021 12:20:43

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:08:26**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '08 Feb 2021'	(b) (4) Olivia Hapanowicz (b) (4)	06 Apr 2021 13:14:26

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:08:26**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '0'	(b) (4) Olivia Hapanowicz (b) (4)	06 Apr 2021 13:14:26

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:08:26**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '0'	(b) (4) Olivia Hapanowicz (b) (4)	06 Apr 2021 13:14:26

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:08:26**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '1'	(b) (4) Olivia Hapanowicz (b) (4)	06 Apr 2021 13:14:26

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:08:26**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '0'	(b) (4) Olivia Hapanowicz (b) (4)	06 Apr 2021 13:14:26

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Immunogenicity Assessment**

Generated On: **09 Jun 2021 17:08:26**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:08:54
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered 'Yes (Y)'	(b) (4) Olivia Hapanowicz (b) (4)	06 Apr 2021 13:14:54

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Immunogenicity Assessment**

Generated On: **09 Jun 2021 17:08:26**

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:08:54
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '08 Feb 2021'	(b) (4) Olivia Hapanowicz (b) (4)	06 Apr 2021 13:14:54

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Immunogenicity Assessment**

Generated On: **09 Jun 2021 17:08:26**

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:08:54
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '15:15'	(b) (4) Olivia Hapanowicz (b) (4)	06 Apr 2021 13:14:54

US3342343

Folder: **Unscheduled 08 Feb 2021**

Form: **Immunogenicity Assessment**

Generated On: **09 Jun 2021 17:08:26**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:08:54
User entered '08 Feb 2021 15:15'	System	06 Apr 2021 13:14:54

US3342343

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:08:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:47
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue, Headache,Joint aches in several joints,Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:23:13
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue, Headache,Joint aches in several joints,Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'These sx are labeled under AE #1 and #3 in source.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	19 Apr 2021 16:32:54
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue, Headache,Joint aches in several joints,Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 09:32:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:01:08
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:44:57

US3342343

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:08:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 20:56:24
	[REDACTED]	
	[REDACTED]	

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:35:59
User entered 'USA-US203-2021-mRNA-1273-P301000014'	System	07 Apr 2021 16:35:53
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 16:35:53

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of cervical spine - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 08:29:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 08:29:29
Data point term sent to Coder	System	22 Mar 2021 16:37:32
Coding entries removed.	Stefanie Mott (b) (4)	22 Mar 2021 16:36:45
	(b) (4)	
	(b) (4)	
User entered 'WORSENING OF OSTEOARTHRITIS OF CERVICAL SPINE' reason for change: Data Entry Error	Stefanie Mott (b) (4)	22 Mar 2021 16:36:45
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc disorder, LLT: Cervical disc disease - version MedDRA\23.0.	Coder Import (b) (4)	04 Dec 2020 16:57:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Dec 2020 16:57:59
Data point term sent to Coder	System	04 Dec 2020 16:57:40
Coding entries removed.	Darrell O'Brien (b) (4)	04 Dec 2020 16:56:53
	(b) (4)	
User entered 'CERVICAL DISC DISEASE' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	04 Dec 2020 16:56:53
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc disorder, LLT: Cervical disc disease - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 04:12:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 04:12:41
Data point term sent to Coder	System	09 Nov 2020 21:01:09
User entered 'Worsening of cervical disc disease'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28
	(b) (4)	
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm event start date of 19 Oct 2020 and surgery did not occur until 31 Mar 2021. If start date is to remain, please confirm symptoms subject experienced at onset.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 19:52:57
Query 'PV Query: Please confirm event start date of 19 Oct 2020 and surgery did not occur until 31 Mar 2021. If start date is to remain, please confirm symptoms subject experienced at onset.' answered with 'Start date to remain. Per subject, sx experienced at onset included back/neck pain and stiffness.' (Site from Safety).	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:14:00
User opened query 'PV Query: Please confirm event start date of 19 Oct 2020 and surgery did not occur until 31 Mar 2021. If start date is to remain, please confirm symptoms subject experienced at onset.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:34:18
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	09 Nov 2020 21:01:31
User entered '19 Oct 2020' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	09 Nov 2020 21:01:31
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	09 Nov 2020 21:00:28
User entered '09 Oct 2020'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 19:19:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 19:19:14
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:19:14
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 19:18:39
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). Signature has been broken.	System	27 Apr 2021 19:18:39
	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:18:39
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:18:39
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	27 Apr 2021 19:18:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4) (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 19:52:20
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	27 Apr 2021 19:18:39
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	27 Apr 2021 19:18:39
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	27 Apr 2021 19:18:19
Signature has been broken.	Ethan Shotton (b) (4)	27 Apr 2021 19:18:19
User entered '02 Apr 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Apr 2021 19:18:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'End date provided per subject.' (Site from Safety).	Ethan Shotton (b) (4)	27 Apr 2021 19:18:04
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:32:25
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	22 Mar 2021 16:36:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:57:06
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	06 Apr 2021 22:12:10
Signature has been broken.	Stefanie Mott (b) (4) [REDACTED]	06 Apr 2021 22:12:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4) [REDACTED]	06 Apr 2021 22:12:10
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	06 Apr 2021 22:10:07
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	Tiffany Lemuz (b) (4) [REDACTED]	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	06 Apr 2021 22:12:10
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	06 Apr 2021 22:12:10
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	06 Apr 2021 22:10:07
Signature has been broken.	Stefanie Mott (b) (4)	06 Apr 2021 22:10:07
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Apr 2021 22:10:07
	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
	(b) (4)	
Signature has been broken.	Stefanie Mott (b) (4)	06 Apr 2021 22:10:07
	(b) (4)	
User entered '31 Mar 2021' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Apr 2021 22:10:07
	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
	(b) (4)	
Signature has been broken.	Stefanie Mott (b) (4)	06 Apr 2021 22:10:07
	(b) (4)	
User entered '02 Apr 2021' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Apr 2021 22:10:07
	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
	(b) (4)	
Signature has been broken.	Stefanie Mott (b) (4)	06 Apr 2021 22:12:10
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Apr 2021 22:12:10
	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Mar 2021 21:14:20
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Feb 2021 20:30:10
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 19:52:07
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'No meds reported for this event.' (Site from Safety).	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:32:22
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:33:02
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:38:23
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED INDICATION TERM IN CON MEDS TO REFLECT THIS AE ' (Site from DM).	Stefanie Mott (b) (4)	18 Mar 2021 14:39:20
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 21:14:20
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Feb 2021 20:30:10

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User entered '1'	(b) (4), (b) (6)	30 Jan 2021 06:02:21
	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Stefanie Mott (b) (4)	22 Mar 2021 16:36:45
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 19:51:45
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Event outcome updated per subject.' (Site from Safety). Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:19:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:18:39
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:33:17
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:00:28

US3342343

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 19:51:33
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'COVID-19 NP swab result negative on 31Mar2021.' (Site from Safety).	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:19:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:32:38
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:32:08
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:57:06
Signature has been broken.	Stefanie Mott (b) (4)	06 Apr 2021 22:10:07
User entered 'pt reports surgery on 31Mar2021. pt was hospitalized for 2 days. Pt prescribed a muscle spasm and pain medication (name and dosage unknown). pt states she had surgery on cervical disc (unsure of exact terminology for type of surgery). Docu-sign sent to obtain medical records.' reason for change: New Information	Stefanie Mott (b) (4)	06 Apr 2021 22:10:07
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = WORSENING OF OSTEOARTHRITIS OF THE CERVICAL SPINE. However, please review and confirm if the AE term should be updated to reflect this worsening condition. Review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:00:24
User closed query 'Per DM CLR: SAE Narrative = MRI . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:00:16
Query 'Per DM CLR: SAE Narrative = MRI . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'MRI ADDED TO CONPROC' (Site from DM).	Stefanie Mott (b) (4)	22 Mar 2021 16:39:23
Query 'Per DM CLR: SAE Narrative = WORSENING OF OSTEOARTHRITIS OF THE CERVICAL SPINE. However, please review and confirm if the AE term should be updated to reflect this worsening condition. Review and reconcile data as appropriate. ' answered with 'NARRATIVE DELETED SINCE THIS IS NOT AN SAE AT THIS TIME. AE TERM UPDATED TO REFLECT WORSENING' (Site from DM).	Stefanie Mott (b) (4)	22 Mar 2021 16:39:16
User entered empty; reason for change New Information	Stefanie Mott (b) (4)	22 Mar 2021 16:38:53
User opened query 'Per DM CLR: SAE Narrative = WORSENING OF OSTEOARTHRITIS OF THE CERVICAL SPINE. However, please review and confirm if the AE term should be updated to reflect this worsening condition. Review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:02:14
User opened query 'Per DM CLR: SAE Narrative = MRI . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:02:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WORSENING OF OSTEOARTHRITIS OF THE CERVICAL SPINE. SUBJECT REPORTS INCREASED PAIN. SHE SAW HER PHYSICIAN FOUR WEEKS AGO FOR AN MRI AND IS PLANNING A SURGERY. REPORTS RECEIVING STEROID INJECTION IN THE CERVICAL SPINE 21 OCT 2020 BUT DOES NOT RECALL THE DETAILS OF THE MEDICATION (DRUG NAME, DOSAGE) DUE TO LANGUAGE BARRIER BETWEEN SHE AND HER PRIMARY CARE PHYSICIAN WHO ADMINISTERED THE TREATMENT, Update: Patient does not have date for planned surgery at this time (patient does not know the procedure but believes it does involve intervertebral discs). Patient told to f/u with CRC when she has more information. DAO 04DEC2020' reason for change: New Information	Darrell O'Brien (b) (4) (b) (4)	04 Dec 2020 16:58:49
User entered 'Worsening of osteoarthritis of the cervical spine. Subject reports increased pain. She saw her physician four weeks ago for an MRI and is planning a surgery. Reports receiving steroid injection in the cervical spine 21 Oct 2020 but does not recall the details of the medication (drug name, dosage) due to language barrier between she and her primary care physician who administered the treatment,'	Tiffany Lemuz (b) (4) (b) (4)	09 Nov 2020 21:00:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 22:12:10
User entered '0'	System	09 Nov 2020 21:00:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 21:00:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 22:12:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovitis, LLT: Synovitis - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 22:59:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 22:59:37
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 21:05:16
User entered 'New onset of symmetrical synovitis of hands and feet'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '26 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05
	[REDACTED]	
	[REDACTED]	

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '1'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05
	[REDACTED]	
	[REDACTED]	

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Subject reports worsening of osteoarthritis in hips, wrists, and ankles for the past 2 weeks. She reports using Toradol to treat.'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 21:05:05

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM). Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'It is not known.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 13:38:49
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	Olivia Hapanowicz (b) (4)	17 Dec 2020 18:08:36
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\23.0.	(b) (4), (b) (6) Coder Import (b) (4)	14 Dec 2020 16:01:01 04 Dec 2020 16:56:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Dec 2020 16:56:58
Data point term sent to Coder	System	04 Dec 2020 16:55:39
Coding entries removed.	Darrell O'Brien (b) (4)	04 Dec 2020 16:55:27
User entered 'ACUTE VIRAL INFECTION' reason for change: Data Entry Error	(b) (4)	04 Dec 2020 16:55:27
User closed query 'Per MM: Please provide symptoms.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:57:16
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 12:36:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 12:36:11
Data point term sent to Coder	System	23 Nov 2020 22:42:07
Query 'Per MM: Please provide symptoms.' answered with 'Symptoms provided ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:42:00
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 22:41:49
User entered 'ACUTE VIRAL INFECTION-Fatigue, Muscle Aches, headache' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 22:41:49

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per MM: Please provide symptoms.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:16:57
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:18:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:18:37
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:09:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:09:38
Data point term sent to Coder	System	09 Nov 2020 21:08:32
User entered 'Acute viral infection'	Tiffany Lemuz (b) (4) [Redacted]	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per CDM: Please confirm if this AE is a solicited adverse reaction based on information provided on pg 32 of CCGs. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 13:56:16
Query 'Per CDM: Please confirm if this AE is a solicited adverse reaction based on information provided on pg 32 of CCGs. Thank you' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	04 Dec 2020 16:55:47
User entered 'No (N)' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	04 Dec 2020 16:55:41
User opened query 'Per CDM: Please confirm if this AE is a solicited adverse reaction based on information provided on pg 32 of CCGs. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:01:54
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	19 Apr 2021 16:26:12
User entered '13 Oct 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	19 Apr 2021 16:26:12
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered '18 Oct 2020' reason for change: Data Entry Error	Tiffany Lemuz (b) (4) [REDACTED]	09 Nov 2020 21:09:09
User entered '13 Oct 2020'	Tiffany Lemuz (b) (4) [REDACTED]	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 16:31:26
Signature has been broken.	Ethan Shotton (b) (4)	19 Apr 2021 16:31:26
User entered '13:38' reason for change: Data Entry Error	Ethan Shotton (b) (4)	19 Apr 2021 16:31:26
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 16:26:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:09:09
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:07:38
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User entered '13 Oct 2020 13:38'	System	19 Apr 2021 16:31:26
User entered empty.	System	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	19 Apr 2021 16:31:26
User entered '28 Oct 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	19 Apr 2021 16:31:26
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:12:10
User entered '27 Oct 2020'	Tiffany Lemuz (b) (4) [Redacted] [Redacted]	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 16:31:26
Signature has been broken.	Ethan Shotton (b) (4)	19 Apr 2021 16:31:26
User entered '16:49' reason for change: Data Entry Error	(b) (4)	
	Ethan Shotton (b) (4)	19 Apr 2021 16:31:26
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	19 Apr 2021 16:26:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:09:09
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 21:07:38
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User entered '28 Oct 2020 16:49'	System	19 Apr 2021 16:31:26
User entered empty.	System	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:39
Query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with "'None" when referring to action taken with investigational product' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:13:26
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 15:12:46
User opened query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:13:10
User entered 'Not Applicable (NOT APPLICABLE)'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	09 Nov 2020 21:09:18
User entered '1' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	09 Nov 2020 21:09:18
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 21:07:38
User entered '0'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Subject reported fatigue, muscle aches, and HA ongoing past day 7 post study vaccine one. Brought in for illness visit. COVID negative. Symptoms resolved.'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User entered '0'	System	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User entered '1'	System	09 Nov 2020 21:07:38

US3342343

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
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.	(b) (4) Coder Import (b) (4)	21 Jan 2021 16:31:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 16:31:04
Data point term sent to Coder	System	21 Jan 2021 16:29:20
User entered 'Hypertension'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '04 Jan 2021'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:28:15

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:28:15

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:40:57
Query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' answered with 'updated in EDC' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 20:25:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Feb 2021 20:25:40
User opened query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:46:36
User entered 'None (NONE)'	Ethan Shotton (b) (4) (b) (4)	21 Jan 2021 16:28:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '1'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:28:15
	(b) (4)	

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 16:28:15

US3342343

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 16:28:15

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 21:17:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 21:17:53
Data point term sent to Coder	System	11 Mar 2021 21:17:02
User entered 'ALLERGIC RHINITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 21:16:38
User entered 'AllerRhinitis'	(b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '07 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User entered empty.	System	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:36:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '15 Mar 2021' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:36:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User entered empty.	System	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	18 Mar 2021 14:36:27
Data Entry Error	Stefanie Mott (b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User entered '0'	System	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01
User entered '0'	System	11 Mar 2021 21:16:01

US3342343

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:01

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:21:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:21:17
Data point term sent to Coder	System	27 Apr 2021 19:35:32
User entered 'Osteoarthritis and post-operative pain after surgery'	Ethan Shotton (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Apr 2021'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

Death

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

None

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 19:35:29

US3342343

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:08:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 19:35:29

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:08:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:47
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:13:53

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
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 Nov 2020 21:15:37
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 Nov 2020 21:15:37
Data point term sent to Coder	System	09 Nov 2020 21:14:40
User entered 'Ibuprofen'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Osteoarthritis'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '500'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'mg (mg)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'once daily (QD)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Oral (ORAL)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '31 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 21:14:38

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 13:04:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 13:04:32
Data point term sent to Coder Coding entries removed.	System Stefanie Mott (b) (4)	18 Mar 2021 14:41:14 18 Mar 2021 14:40:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:30:41
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 Nov 2020 04:30:41
Data point term sent to Coder User entered 'Toradol'	System Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:41 09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered 'NEW ONSET OF SYMMETRICAL SYNOVITIS OF HANDS AND FEET' reason for change: Data Entry Error	Stefanie Mott (b) (4)	18 Mar 2021 14:40:50
User entered 'Osteoarthritis'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '10'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'mg (mg)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'as needed (PRN)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Oral (ORAL)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '31 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:15:34

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:12:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:12:28
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:40:56
Data point term sent to Coder	System	19 Mar 2021 12:22:04
User closed query 'Per CDM Coding: for CM term -CORTICOSTEROID, Please update the term with the brand or active ingredient name(s) of medication. ' (Site from System).	System	19 Mar 2021 12:21:19
Query 'Per CDM Coding: for CM term -CORTICOSTEROID, Please update the term with the brand or active ingredient name(s) of medication. ' answered with 'please see note under dose unit - per pt, this information is unknown and this is how the medication will be reported.' (Site from System).	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 12:21:19
User opened query 'Per CDM Coding: for CM term -CORTICOSTEROID, Please update the term with the brand or active ingredient name(s) of medication. ' (Site from System).	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:58:00
Data point term sent to Coder	System	18 Mar 2021 14:39:12
Coding entries removed.	Stefanie Mott (b) (4)	18 Mar 2021 14:38:51
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:53:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:53:42
Data point term sent to Coder	System	09 Nov 2020 21:20:49

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Corticosteroid'	Tiffany Lemuz (b) (4) [REDACTED] [REDACTED]	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'cervical disc disease AE' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	18 Mar 2021 14:38:51
User entered 'Osteoarthritis'	Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '1'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Other (OTHER)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'dose *Subject did not know the specific details of the steroid injection (drug name, dosage). Reports language barrier between themselves and their primary care physician who administered the inj.'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'once (ONCE)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Other (OTHER)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Epidural'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '21 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '21 Oct 2020'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User entered empty.	System	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User entered empty.	System	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:05
User entered empty.	System	09 Nov 2020 21:20:18

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
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)	21 Jan 2021 16:24:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:24:04
Data point term sent to Coder	System	21 Jan 2021 16:22:55
User entered 'Lisinopril'	Ethan Shotton (b) (4) (b) (4)	21 Jan 2021 16:22:01

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered 'Hypertension AE'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered '2.5'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered 'mg (mg)'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered 'once daily (QD)'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered '04 Jan 2021'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	21 Jan 2021 16:22:01
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 16:22:01

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 16:22:01

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 16:22:01

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
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)	11 Mar 2021 21:44:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Mar 2021 21:44:55
Data point term sent to Coder User entered 'Ibuprofen'	System Ethan Shotton (b) (4)	11 Mar 2021 21:44:42 11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Allergic Rhinitis AE'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '600'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'mg (mg)'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'once (ONCE)'	(b) (4) Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered empty.	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '11 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '0'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered '11 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	Ethan Shotton (b) (4)	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User entered empty.	System	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User entered empty.	System	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:24:38
User entered empty.	System	11 Mar 2021 21:44:08

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

Name of Medication

Audit	User	Time (GMT)
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)	29 Apr 2021 22:21:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 22:21:16
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	28 Apr 2021 16:42:58
Data point term sent to Coder	System	27 Apr 2021 19:37:37
User entered 'Ibuprofen'	Ethan Shotton (b) (4) (b) (4)	27 Apr 2021 19:37:28

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered 'Osteoarthritis and PostOperative Pain After Surgery'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered '200'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'mg (mg)'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'as needed (PRN)'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered '02 Apr 2021'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	27 Apr 2021 19:37:28
	(b) (4)	

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:37:28

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:37:28

US3342343

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:37:28

US3342343

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:08:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
Signature has been broken.	(b) (4) Olivia Hapanowicz (b) (4)	22 Mar 2021 16:26:51
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Olivia Hapanowicz (b) (4)	22 Mar 2021 16:26:51
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:40:56
User entered 'No (N)'	(b) (4) Ethan Shotton (b) (4)	08 Mar 2021 13:49:38

US3342343

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '19 Oct 2020'	(b) (4) Olivia Hapanowicz (b) (4)	22 Mar 2021 16:28:26
	(b) (4)	

US3342343

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
	(b) (4)	
User entered 'MRI - CERVICAL SPINE' reason for change: Data Entry Error	Stefanie Mott (b) (4)	22 Mar 2021 16:39:52
	(b) (4)	
User entered 'MRI - cervical'	Olivia Hapanowicz (b) (4)	22 Mar 2021 16:28:26
	(b) (4)	

US3342343

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'Adverse Event (AE)'	(b) (4) Olivia Hapanowicz (b) (4)	22 Mar 2021 16:28:26
	(b) (4)	

US3342343

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:26

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered empty.	(b) (4) Olivia Hapanowicz (b) (4)	22 Mar 2021 16:28:26
	(b) (4)	

US3342343

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:08:26

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:47:23
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered '09 Nov 2020'	(b) (4) Eileen Euperio (b) (4)	14 Dec 2020 20:34:39

US3342343

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:08:26

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:47:23
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User entered 'AE (specify) (ADVERSE EVENT)'	Eileen Euperio (b) (4)	14 Dec 2020 20:34:39

US3342343

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:08:26

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:47:23
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:12:10
User closed query 'Per CDM: Please clarify the meaning of "2". Please clarify if this is AE#2 and if yes, then please consider changing that to "AE#2" or clarify otherwise. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 17:11:01
Query 'Per CDM: Please clarify the meaning of "2". Please clarify if this is AE#2 and if yes, then please consider changing that to "AE#2" or clarify otherwise. Thank you!' answered with 'Updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	15 Jan 2021 17:25:58
User entered 'AE#2' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	15 Jan 2021 17:25:54
User opened query 'Per CDM: Please clarify the meaning of "2". Please clarify if this is AE#2 and if yes, then please consider changing that to "AE#2" or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 11:14:36
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:34:52
User entered '2' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	14 Dec 2020 20:34:52
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:34:39
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Dec 2020 20:34:39

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:23
User entered 'USA-US203-2021-MRNA-1273-P301000014'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Paul'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Pickrell'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 19:54:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered 'US'	(b) (4) System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 19:56:02
User entered '1'	System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:23
User entered 'USA-US203-2021-MRNA-1273-P301000014'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Paul'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Pickrell'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 19:54:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered 'US'	(b) (4) System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 19:56:02
User entered '1'	System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '07/Apr/2021 12:36'	(b) (4) System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 19:54:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:23
User entered 'USA-US203-2021-MRNA-1273-P301000014'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Paul'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Pickrell'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 19:54:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered 'US'	(b) (4) System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 19:56:02
User entered '1'	System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 19:54:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:23
User entered 'USA-US203-2021-MRNA-1273-P301000014'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'No (N)'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Paul'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:36:29
User entered 'Pickrell'	System	07 Apr 2021 16:35:53

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 19:54:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:06
User entered 'US'	(b) (4) System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 19:56:02
User entered '1'	System	07 Apr 2021 16:36:54

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:08:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered '27/Apr/2021 15:56'	(b) (4) System	27 Apr 2021 19:56:02

US3342343

Folder: SAE USA-US203-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:08:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:42:58
User entered '1'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:56:02