

US3852015 (Prod: Ascension St. Vincent Birmingham)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:03:24

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US3852015

Form: Participant Creation

Data signed: (b) (4) 09 Feb 2021 10:23:32

Generated On: 10 Jun 2021 10:03:24

Participant ID

US3852015

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

US3852015

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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

Visit date (dd MMM yyyy)	24 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3852015

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3852015

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3852015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Were any significant conditions reported?

Yes ☒

No ☐

US3852015

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3852015

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3852015

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3852015

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Condition	INSOMNIA
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)	

US3852015

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3852015

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Condition	OOPHORECTOMY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Condition	LOW ESTROGEN LEVEL
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Condition	BOTOX
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3852015

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	10:07 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 10:07
Height (xxx.x)	62 in
Weight (xxx.x)	139.2 lb
BMI (xxx.x)	25.51325 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Date of assessment (dd MMM yyyy) 24 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1995

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) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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) 09 Feb 2021 10:23:41

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3852015

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 188003

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) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	12:12 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 12:12
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:27
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3852015

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 13:47 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 13:47

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) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

12:37 (24 HR)

Collection date and time (derived)

24 AUG 2020 12:37

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:00	24 AUG 2020 13:00
Nasopharyngeal Swab 2	No		

US3852015

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 14:20

PC Open Date & Time

24 AUG 2020 14:07

PC Close Date & Time

24 AUG 2020 16:37

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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 97.7 °F

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

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

PC Time Stamp	24 AUG 2020 21:10
PC Open Date & Time	24 AUG 2020 17:32
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 21:04

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 22:04

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 22:14

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:45

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 23:59

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 20:26

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

24 AUG 2020 14:22

PC Open Date & Time

24 AUG 2020 14:07

PC Close Date & Time

24 AUG 2020 16:37

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

24 AUG 2020 21:10

PC Open Date & Time

24 AUG 2020 17:32

PC Close Date & Time

25 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 21:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 22:04

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 22:14

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:45

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 23:59

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:27

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 14:24
PC Open Date & Time	24 AUG 2020 14:07
PC Close Date & Time	24 AUG 2020 16:37

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 21:11
PC Open Date & Time	24 AUG 2020 17:32
PC Close Date & Time	25 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

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 ☒

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 21:05
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3026

EAB) (1725)

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 22:04
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 3026

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 22:14
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

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 ☒

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:45
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 3026

EAB) (1725)

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 00:00
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 3026

EAB) (1725)

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:27
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3852015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:15
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:39 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:39
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3852015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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.

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 10:04 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 10:04

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

What was the frequency of the study treatment dosing? ONCE

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

US3852015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

9:33 (24 HR)

Collection date and time (derived)

21 SEP 2020 9:33

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:30	21 SEP 2020 9:30
Nasopharyngeal Swab 2	No		

US3852015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp 21 SEP 2020 10:43

PC Open Date & Time 21 SEP 2020 10:24

PC Close Date & Time 21 SEP 2020 12:54

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	21 SEP 2020 20:27
PC Open Date & Time	21 SEP 2020 13:49
PC Close Date & Time	22 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 20:00

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 19:52

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 17:59

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:26

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 20:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:27

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

21 SEP 2020 10:45

PC Open Date & Time

21 SEP 2020 10:24

PC Close Date & Time

21 SEP 2020 12:54

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

21 SEP 2020 20:27

PC Open Date & Time

21 SEP 2020 13:49

PC Close Date & Time

22 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:00

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 19:52

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 18:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 20:27

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 20:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 20:28

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:46
PC Open Date & Time	21 SEP 2020 10:24
PC Close Date & Time	21 SEP 2020 12:54

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 20:28
PC Open Date & Time	21 SEP 2020 13:49
PC Close Date & Time	22 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

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 ☒

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 20:01
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

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 ☒

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 19:53
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

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 ☒

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 18:01
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

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 ☒

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:27
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 3026

EAB) (1725)

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 20:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

107 of 3026

EAB) (1725)

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:28
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3852015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

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

PT WAS NOT ASSIGNED TO A
NURSE

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:23:42

Generated On: 10 Jun 2021 10:03:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Feb 2021 10:23:42

Generated On: 10 Jun 2021 10:03:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 09:09
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3852015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:23:42

Generated On: 10 Jun 2021 10:03:24

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.

US3852015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Feb 2021 10:23:42

Generated On: 10 Jun 2021 10:03:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	09:40 (24 HR)
Collection date and time (derived)	19 OCT 2020 09:40

US3852015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:42

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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	28 NOV 2020 15:57:58
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

05 DEC 2020 17:59:47

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 13:16:08
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	23 DEC 2020 23:58:15
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 00:07:56

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 08:54:10

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 16:54:55
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

20 JAN 2021 07:26:44

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

27 JAN 2021 09:32:55

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 21:01:11
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 15:20:34

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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	17 FEB 2021 07:37:25
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 06:12:01

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 07:00:57
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 11:40:49
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 23:26:09

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 15:00:52

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 APR 2021 18:19:46
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 00:47:51

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 09:49:31
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 08:28:47

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 06:50:34

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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°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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2021 00:01
Patient Cloud Close Date & Time	01 AUG 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

Patient Cloud Open Date & Time	22 DEC 2021 00:01
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Patient Cloud Close Date & Time	26 DEC 2021 23:59
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US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

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09 FEB 2022 00:01

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13 FEB 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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20 FEB 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

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23 FEB 2022 00:01

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27 FEB 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

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13 MAR 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

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17 APR 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

Patient Cloud Open Date & Time	24 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

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

Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3852015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:03:24

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
Yes	No	01 MAR 2021 06:05:26

US3852015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

PATIENT IS CURRENTLY
GETTING CONVALESCENT
CALLS

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

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

Visit date (dd MMM yyyy)	15 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	VISIT4
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US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3852015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

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.

US3852015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	09:11 (24 HR)
Collection date and time (derived)	15 MAR 2021 09:11

US3852015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3852015

Folder: Covid-19 Assessment (2)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Date of Contact	18 DEC 2020
Time of Contact	10:15
Date and Time of Contact (derived)	18 DEC 2020 10:15
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 18 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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"/>

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	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 DEC 2020
------	-------------

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

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

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

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

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

Cough	None <input 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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US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 18 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 18 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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 18 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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 18 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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 18 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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 18 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 09 Feb 2021 10:23:39

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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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Form: Symptom Log (12)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Form: Symptom Log (12)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 09 Feb 2021 10:23:39

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Form: Symptom Log (15)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 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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US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98 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 18 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	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	1 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97 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 18 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Symptom Day

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

	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"/>

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Date of Visit	18 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	18 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 DEC 2020
Day 5	Yes	22 DEC 2020
Day 7	Yes	24 DEC 2020
Day 9	Yes	26 DEC 2020
Day 14	Yes	31 DEC 2020
Day 21	Yes	7 JAN 2021
Day 28	Yes	14 JAN 2021

US3852015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 DEC 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

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 DEC 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	18 DEC 2020 10:36
Height (xxx.x)	62 in
Weight (xxx.x)	136 lb
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3852015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 DEC 2020

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

US3852015

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 DEC 2020

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

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)	08:30 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 08:30
Height (xxx.x)	62 in
Weight (xxx.x)	142 lb
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:23:39

Generated On: 10 Jun 2021 10:03:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3852015

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 09 Feb 2021 10:23:33

Generated On: 10 Jun 2021 10:03:24

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 JAN 2021

US3852015

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

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

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

Visit date (dd MMM yyyy)	19 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3852015

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 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>)	19 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

US3852015

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Height	
Weight	
BMI (xxx.x)	

US3852015

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Height	
Weight	
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)	19 JAN 2021
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 11:56
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3852015

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Feb 2021 10:23:41

Generated On: 10 Jun 2021 10:03:24

Height	
Weight	
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)	19 JAN 2021
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 12:45
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3852015

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

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

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.

US3852015

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

Form: Exposure

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 12:10 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 12:10

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

US3852015

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

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

Collection date (dd MMM yyyy)	19 JAN 2021
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Collection time (00:00-23:59)	12:00 (24 HR)
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Collection date and time (derived)	19 JAN 2021 12:00
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US3852015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

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

Collection date (dd MMM yyyy)	19 JAN 2021
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Collection time (00:00 - 23:59)	11:45
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Collection Date and Time (derived)	19 JAN 2021 11:45
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US3852015

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

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:23:40

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

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)	17 FEB 2021
Time of assessment (00:00-23:59)	08:43 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 08:43
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

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)	17 FEB 2021
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 09:20
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3852015

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

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.

US3852015

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

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) 17 FEB 2021

What was the treatment time? (00:00-23:59) 08:46 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 08:46

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

US3852015

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852015

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 04:28:02

Generated On: 10 Jun 2021 10:03:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852015

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:55 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 08:55
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3852015

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

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.

US3852015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 20:42:25

Generated On: 10 Jun 2021 10:03:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	09:11 (24 HR)
Collection date and time (derived)	15 MAR 2021 09:11

US3852015

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Feb 2021 10:23:33

Generated On: 10 Jun 2021 10:03:24

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

AEID	USA-US076-2020-MRNA-1273-P30 1000011
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	2 JAN 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"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

AEID

Adverse event

SCIATICA LEFT LEG FROM
CHRONIC BACK PAIN

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)

27 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 JAN 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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

AEID	USA-US076-2021-MRNA-1273-P30 1000003
Adverse event	WORSENING BACK PAIN
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)	28 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)	31 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	28 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	31 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	ADMITTED TO HOSPITAL FOR BACK PAIN ON 3/28/31, LAMINECTOMY/DISCECTOMY OF L5 ON 3/31/21, DISCHARGED 3/31/21
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 21:13:46

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Feb 2021 10:23:33

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS TOOTH
EXTRACTION (SUBJECT HAS
PRIOR JOINT REPLACEMENT)

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication IBUPOFEN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS TOOTH
EXTRACTION FOR SWELLING

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		6 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		6 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication LOW ESTROGEN LEVEL

Dose per administration 0.5

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1997	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication NASAL CONGESTION DUE TO
COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

	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)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication ROBAXIN

Prophylaxis Yes ☐
No ☒

Indication SCIATICA LEFT LEG

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

	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)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication SCIATICA LEFT LEG

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

473 of 3026

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

	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)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PAIN

Dose per administration 5/325

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)

475 of 3026

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

	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 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 8 APR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Feb 2021 10:23:33

Generated On: 10 Jun 2021 10:03:24

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 20:31:27

Generated On: 10 Jun 2021 10:03:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 AUG 2020	TOOTH EXTRACTION	Other	DENTAL WORK
31 MAR 2021	LAMINECTOMY/DISCECTOMY L5	Adverse Event	

US3852015

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:03:24

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

Case Report Form

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

US3852015

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:03:24

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

US3852015

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:03:24

Date of dosing discontinuation (dd MMM yyyy)

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

US3852015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:03:24

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 ☐

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/DEC/2020 11:05
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

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/JAN/2021 13:20
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

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 17:41
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

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:17
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

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/APR/2021 13:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
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)	19/APR/2021 12:52
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

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 21:13:46

Generated On: 10 Jun 2021 10:03:24

SAEID	USA-US076-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
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)	30/APR/2021 13:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3852015 (Prod: Ascension St. Vincent Birmingham)

US3852015

Form: Participant Creation

Generated On: 10 Jun 2021 10:03:24

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'US3852015'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:04:32

US3852015

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 17:35:32

US3852015

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:04:33

US3852015

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Clinic (Clinic)'	Jessica Bartlett (b) (4)	24 Aug 2020 17:35:32

US3852015

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'SCRN'	System	24 Aug 2020 17:35:32

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:04:34

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '69'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'YEARS'	System	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '69'	System	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Female (F)'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'I'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 17:36:00

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	Jessica Bartlett (b) (4)	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Aug 2020'	System	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '2020'	System	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Amendment 2 (2)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:28:35

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:04:33

US3852015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'I'	System	24 Aug 2020 18:28:42

US3852015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:03:24

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:28:42

US3852015

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:03:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:29:12

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:44:09
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Patient indicated at screening that she is not currently being treated for her asthma' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:09:19
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:51:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 20:30:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 20:30:37
Data point term sent to Coder	System	24 Aug 2020 20:30:18
User entered 'Asthma'	Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'UN UNK 1996'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 1996'	System	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '1996'	System	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	24 Aug 2020 20:29:40

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:32:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:32:40
Data point term sent to Coder	System	24 Aug 2020 20:31:20
User entered 'Hyperlipidemia'	Caitlin roll (b) (4)	24 Aug 2020 20:31:11
	(b) (4)	

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'UN UNK 2005'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 2005'	System	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '2005'	System	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	24 Aug 2020 20:31:11

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:44:16
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'corresponding medication added to con med eCRF' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:07:46
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 09:00:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 09:00:31
Data point term sent to Coder	System	16 Oct 2020 08:59:10
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 08:58:14
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 08:58:14
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:52:39
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Aug 2020 20:33:41
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 20:32:21
User entered 'Hypothyroidism'	Caitlin roll (b) (4)	24 Aug 2020 20:31:48
	(b) (4)	

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'UN UNK 1990'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:48

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:48

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:48

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4)	24 Aug 2020 20:31:48
	Caitlin roll (b) (4)	
	(b) (4)	

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:31:48

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 1990'	System	24 Aug 2020 20:31:48

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '1990'	System	24 Aug 2020 20:31:48

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	24 Aug 2020 20:31:48

US3852015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	24 Aug 2020 20:31:48

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:34:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:34:43
Data point term sent to Coder	System	24 Aug 2020 20:33:22
User entered 'Insomnia'	Caitlin roll (b) (4)	24 Aug 2020 20:32:22
	(b) (4)	

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'UN UNK 2010' reason for change:	(b) (4)	
Data Entry Error	Leslie Edwards (b) (4)	13 Nov 2020 16:12:50
User entered 'UN UNK 2017'	(b) (4)	
	Caitlin roll (b) (4)	24 Aug 2020 20:32:22
	(b) (4)	

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:32:22

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:32:22

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:32:22

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:32:22

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 2010'	System	13 Nov 2020 16:12:50
User entered 'Jan 2017'	System	24 Aug 2020 20:32:22

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '2010'	System	13 Nov 2020 16:12:50
User entered '2017'	System	24 Aug 2020 20:32:22

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	24 Aug 2020 20:32:22

US3852015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	24 Aug 2020 20:32:22

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
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.	(b) (4) Coder Import (b) (4)	24 Aug 2020 20:35:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:35:45
Data point term sent to Coder	System	24 Aug 2020 20:34:24
User entered 'Hysterectomy'	Caitlin roll (b) (4)	24 Aug 2020 20:33:41
	(b) (4)	

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'UN UNK 1995'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'UN UNK 1995'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 1995'	System	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '1995'	System	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 1995'	System	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '1995'	System	24 Aug 2020 20:33:41

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Oophorectomy, LLT: Oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:36:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:36:37
Data point term sent to Coder	System	24 Aug 2020 20:35:29
User entered 'oophorectomy'	Caitlin roll (b) (4)	24 Aug 2020 20:34:38
	(b) (4)	

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'UN UNK 1995'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'UN UNK 1995'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 1995'	System	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '1995'	System	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 1995'	System	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '1995'	System	24 Aug 2020 20:34:38

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User coded data point as SOC: Investigations, HLGt: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood oestrogen decreased, LLT: Estrogen low - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 06:05:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 06:05:46
Data point term sent to Coder	System	13 Nov 2020 16:12:57
User entered 'Low estrogen level'	Leslie Edwards (b) (4)	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'un UNK 1995'	(b) (4) Leslie Edwards (b) (4)	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Leslie Edwards (b) (4)	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Leslie Edwards (b) (4)	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Leslie Edwards (b) (4)	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Leslie Edwards (b) (4)	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 1995'	System	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '1995'	System	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	13 Nov 2020 16:12:37

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 18:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 18:25:10
Data point term sent to Coder	System	19 Jan 2021 18:24:25
User entered 'Chronic back pain'	Leslie Edwards (b) (4)	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Leslie Edwards (b) (4)	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'I'	Leslie Edwards (b) (4)	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Leslie Edwards (b) (4)	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Leslie Edwards (b) (4)	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Leslie Edwards (b) (4)	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered empty.	System	19 Jan 2021 18:24:14

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Mar 2021 13:35:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 13:35:27
Data point term sent to Coder	System	25 Mar 2021 13:34:33
User entered 'Botox'	Leslie Edwards (b) (4) (b) (4)	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'un UNK 2018'	Leslie Edwards (b) (4)	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '0'	(b) (4) Leslie Edwards (b) (4)	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'No (N)'	(b) (4) Leslie Edwards (b) (4)	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'un UNK 2018'	Leslie Edwards (b) (4)	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '0'	(b) (4) Leslie Edwards (b) (4)	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 2018'	System	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '2018'	System	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'Jan 2018'	System	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:03:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '2018'	System	25 Mar 2021 13:33:34

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	Jessica Bartlett (b) (4)	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '10:07'	Jessica Bartlett (b) (4)	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered '24 Aug 2020 10:07'	System	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '62' in	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:31:39
DataPoint set to visible.	(b) (4) System	24 Aug 2020 18:28:42

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '139.2' lb	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:31:39
DataPoint set to visible.	(b) (4) System	24 Aug 2020 18:28:42

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
Amendment Manager: User entered '25.51325'	System	17 Sep 2020 00:21:28
User entered '25.5'	System	24 Aug 2020 18:31:39
DataPoint set to visible.	System	24 Aug 2020 18:28:42

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'kg/m2'	System	24 Aug 2020 18:31:39
DataPoint set to visible.	System	24 Aug 2020 18:28:42

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 20:14:43
User entered '98.4' F	Leslie Edwards (b) (4)	24 Aug 2020 18:31:39
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'infrared forehead'	Jessica Bartlett (b) (4)	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 20:14:43
User entered '53'	Leslie Edwards (b) (4)	24 Aug 2020 18:31:39
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'bpm'	System	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 20:14:43
User entered '16'	Leslie Edwards (b) (4)	24 Aug 2020 18:31:39
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'breaths/min'	System	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 20:14:43
User entered '138'	Leslie Edwards (b) (4)	24 Aug 2020 18:31:39
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'mmHg'	System	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 20:14:43
User entered '83'	Leslie Edwards (b) (4)	24 Aug 2020 18:31:39
	(b) (4)	

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User entered 'mmHg'	System	24 Aug 2020 18:31:39

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40

US3852015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40

US3852015

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:31:48

US3852015

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	Jessica Bartlett (b) (4)	24 Aug 2020 18:31:48

US3852015

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:15

US3852015

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:24

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:15

US3852015

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:24

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:46:42
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' answered with 'Condition/reason that subject underwent hysterectomy is unknown' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 04:13:15
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 05:11:13
User entered 'Surgically sterile (SURGICALLY STERILE)'	Jessica Bartlett (b) (4) (b) (4)	24 Aug 2020 18:32:15

US3852015

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:24

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:15

US3852015

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'un UNK 1995'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:15

US3852015

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:24

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:15

US3852015

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:15

US3852015

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:24

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:15

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46
	(b) (4)	

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'I'	Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46

US3852015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:54:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 18:32:46
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 23:20:56
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 23:20:47
User entered 'Yes (Y)'	Jessica Bartlett (b) (4) (b) (4)	24 Aug 2020 18:29:27

US3852015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 23:20:59
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 23:20:47
User entered '24 Aug 2020'	Jessica Bartlett (b) (4) (b) (4)	24 Aug 2020 18:29:27

US3852015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 23:21:01
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 23:20:47
User entered 'Clinic (Clinic)'	Jessica Bartlett (b) (4) (b) (4)	24 Aug 2020 18:29:27

US3852015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'VISIT1'	System	24 Aug 2020 18:29:27

US3852015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:34:23

US3852015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:24

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '188003'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:34:23

US3852015

Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:34:23

US3852015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:24

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)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 16:00:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 16:00:07
User entered 'No (N)' reason for change: Data Entry Error	Caitlin roll (b) (4)	26 Aug 2020 16:00:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:33:49
User entered empty; reason for change Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:33:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 18:29:50
User entered 'No (N)' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:40
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:40
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:24

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)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 16:00:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 16:00:07
User entered 'No (N)' reason for change: Data Entry Error	Caitlin roll (b) (4)	26 Aug 2020 16:00:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:33:49
User entered empty; reason for change Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:33:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 18:29:50
User entered 'No (N)' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:40
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:40
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Randomization

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Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 16:00:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 16:00:07
User entered 'No (N)' reason for change: Data Entry Error	Caitlin roll (b) (4)	26 Aug 2020 16:00:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:33:49
User entered empty; reason for change Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:33:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 18:29:50
User entered 'No (N)' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:40
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:40
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 16:00:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 16:00:07
User entered 'No (N)' reason for change: Data Entry Error	Caitlin roll (b) (4)	26 Aug 2020 16:00:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:33:49
User entered empty; reason for change Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:33:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 18:29:50
User entered 'No (N)' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:40
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:40
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 16:00:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 16:00:07
User entered 'No (N)' reason for change: Data Entry Error	Caitlin roll (b) (4)	26 Aug 2020 16:00:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:33:49
User entered empty; reason for change Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:33:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 18:29:50
User entered 'No (N)' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:29:40
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:29:40
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Randomization

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[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Lisa Huse (b) (4)	21 Sep 2020 21:15:20
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:09
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:41:09

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Nov 2020 13:29:22
User entered '62' in	Leslie Edwards (b) (4)	24 Aug 2020 19:52:42
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Nov 2020 13:29:22
User entered '139.2' lb	Leslie Edwards (b) (4)	24 Aug 2020 19:52:42
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Nov 2020 13:29:22
User entered '62' in	Leslie Edwards (b) (4)	24 Aug 2020 19:52:42
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Nov 2020 13:29:22
User entered '139.2' lb	Leslie Edwards (b) (4)	24 Aug 2020 19:52:42
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User accepted default value 'Pre-Dose (PREDOSE)'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '12:12'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '24 Aug 2020 12:12'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98.4' F	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'infrared/forehead'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '53'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'bpm'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '16'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'breaths/min'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '138'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '83'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Nov 2020 13:29:22
User entered '62' in	Leslie Edwards (b) (4)	24 Aug 2020 19:52:42
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Nov 2020 13:29:22
User entered '139.2' lb	Leslie Edwards (b) (4)	24 Aug 2020 19:52:42
	Jessica Bartlett (b) (4)	
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User accepted default value 'Post-Dose (POSTDOSE)'	Jessica Bartlett (b) (4) (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '14:27'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '24 Aug 2020 14:27'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	24 Aug 2020 19:52:53
User entered '97.3' F reason for change: Data Entry Error	System	24 Aug 2020 19:52:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42
User entered '97.3' (non-conformant).	(b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'infrared/forehead'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '52'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'bpm'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '16'	(b) (4) Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'breaths/min'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '140'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '84'	Jessica Bartlett (b) (4)	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	24 Aug 2020 19:52:42

US3852015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:03

US3852015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:03

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

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 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	Jessica Bartlett (b) (4)	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '13:47'	Jessica Bartlett (b) (4)	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '24 Aug 2020 13:47'	System	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Right Arm (RIGHT ARM)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'ONCE'	System	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 18:47:20

US3852015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:23

US3852015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Aug 2020'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:23

US3852015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '12:37'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:23

US3852015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '24 Aug 2020 12:37'	System	24 Aug 2020 18:36:23

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:03:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	24 Aug 2020 18:36:53
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	24 Aug 2020 18:36:53
User entered '24 Aug 2020' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:53
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	24 Aug 2020 18:36:47
User entered empty.	System	24 Aug 2020 18:36:47
	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:47
	(b) (4)	

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessica Bartlett (b) (4) (b) (4)	24 Aug 2020 18:36:47

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:47

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '13:00'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:47

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '24 Aug 2020 13:00'	System	24 Aug 2020 18:36:53
User entered empty.	System	24 Aug 2020 18:36:47

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:47

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:47

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Jessica Bartlett (b) (4)	24 Aug 2020 18:36:47

US3852015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered empty.	System	24 Aug 2020 18:36:47

US3852015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	24 Aug 2020 19:53:07

US3852015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	24 Aug 2020 19:53:07

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T14:19:41', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '555eb4af-1c72-4998-b782-665d83fd6a78' User entered 'Yes (Y)'	System	24 Aug 2020 19:21:07
	System	24 Aug 2020 19:21:07

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:19:51', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '555eb4af-1c72-4998-b782-665d83fd6a78' User entered '97.3'	System	24 Aug 2020 19:21:07
	System	24 Aug 2020 19:21:07

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T14:20:35', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '555eb4af-1c72-4998-b782-665d83fd6a78' User entered 'No (N)'	System	24 Aug 2020 19:21:07
	System	24 Aug 2020 19:21:07

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T14:20:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '555eb4af-1c72-4998-b782-665d83fd6a78' User entered '24 Aug 2020 14:20'	System	24 Aug 2020 19:21:07
	System	24 Aug 2020 19:21:07

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 14:07'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 16:37'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:09:50', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '22c38a81-d884-41a9-9eb0-7e20e2c85bad' User entered 'Yes (Y)'	System	25 Aug 2020 02:10:20
	System	25 Aug 2020 02:10:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T21:09:59', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '22c38a81-d884-41a9-9eb0-7e20e2c85bad' User entered '97.7'	System	25 Aug 2020 02:10:20
	System	25 Aug 2020 02:10:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:10:04', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '22c38a81-d884-41a9-9eb0-7e20e2c85bad' User entered 'No (N)'	System	25 Aug 2020 02:10:20
	System	25 Aug 2020 02:10:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:10:17', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '22c38a81-d884-41a9-9eb0-7e20e2c85bad' User entered '24 Aug 2020 21:10'	System	25 Aug 2020 02:10:20
	System	25 Aug 2020 02:10:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 17:32'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 2'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:04:33', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1c75a8c9-63e1-4b85-90fd-da9ff7a1e27b' User entered 'Yes (Y)'	System	26 Aug 2020 02:05:05
	System	26 Aug 2020 02:05:05

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-25T21:04:42', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1c75a8c9-63e1-4b85-90fd-da9ff7a1e27b' User entered '97.6'	System	26 Aug 2020 02:05:05
	System	26 Aug 2020 02:05:05

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:04:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1c75a8c9-63e1-4b85-90fd-da9ff7a1e27b' User entered 'No (N)'	System	26 Aug 2020 02:05:05
	System	26 Aug 2020 02:05:05

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:04:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1c75a8c9-63e1-4b85-90fd-da9ff7a1e27b' User entered '25 Aug 2020 21:04'	System	26 Aug 2020 02:05:05
	System	26 Aug 2020 02:05:05

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 3'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:03:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '0684b974-2c24-474c-9781-f9aa83faf1bd' User entered 'Yes (Y)'	System	27 Aug 2020 03:04:11
	System	27 Aug 2020 03:04:11

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:03:56', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '0684b974-2c24-474c-9781-f9aa83faf1bd' User entered '97.6'	System	27 Aug 2020 03:04:11
	System	27 Aug 2020 03:04:11

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:04:02', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '0684b974-2c24-474c-9781-f9aa83faf1bd'	System	27 Aug 2020 03:04:11
User entered 'No (N)'	System	27 Aug 2020 03:04:11

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:04:08', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '0684b974-2c24-474c-9781-f9aa83faf1bd' User entered '26 Aug 2020 22:04'	System	27 Aug 2020 03:04:11
	System	27 Aug 2020 03:04:11

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 4'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:13:47', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '42aa6dcc-52b3-4886-b20d-5c8095d2d834' User entered 'Yes (Y)'	System	28 Aug 2020 03:14:03
	System	28 Aug 2020 03:14:03

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-27T22:13:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '42aa6dcc-52b3-4886-b20d-5c8095d2d834' User entered '97.4'	System	28 Aug 2020 03:14:03
	System	28 Aug 2020 03:14:03

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:13:56', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '42aa6dcc-52b3-4886-b20d-5c8095d2d834' User entered 'No (N)'	System	28 Aug 2020 03:14:03
	System	28 Aug 2020 03:14:03

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:01', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '42aa6dcc-52b3-4886-b20d-5c8095d2d834' User entered '27 Aug 2020 22:14'	System	28 Aug 2020 03:14:03
	System	28 Aug 2020 03:14:03

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 5'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-28T20:44:41', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '78d066de-b280-4c5b-ad2d-5ca999912379' User entered 'Yes (Y)'	System	29 Aug 2020 01:45:17
	System	29 Aug 2020 01:45:17

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:44:51', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '78d066de-b280-4c5b-ad2d-5ca999912379' User entered '97.5'	System	29 Aug 2020 01:45:17
	System	29 Aug 2020 01:45:17

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-28T20:45:08', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '78d066de-b280-4c5b-ad2d-5ca999912379' User entered 'No (N)'	System	29 Aug 2020 01:45:17
	System	29 Aug 2020 01:45:17

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:45:13', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '78d066de-b280-4c5b-ad2d-5ca999912379' User entered '28 Aug 2020 20:45'	System	29 Aug 2020 01:45:17
	System	29 Aug 2020 01:45:17

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 6'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:11', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '07c5c2be-5f6b-4342-b153-8c282b94ce28' User entered 'Yes (Y)'	System	30 Aug 2020 04:59:30
	System	30 Aug 2020 04:59:30

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:16', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '07c5c2be-5f6b-4342-b153-8c282b94ce28' User entered '97.4'	System	30 Aug 2020 04:59:30
	System	30 Aug 2020 04:59:30

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:20', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '07c5c2be-5f6b-4342-b153-8c282b94ce28' User entered 'No (N)'	System	30 Aug 2020 04:59:30
	System	30 Aug 2020 04:59:30

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:26', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '07c5c2be-5f6b-4342-b153-8c282b94ce28' User entered '29 Aug 2020 23:59'	System	30 Aug 2020 04:59:30
	System	30 Aug 2020 04:59:30

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 7'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:26:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '194b0995-c754-47b6-ad6e-0c6744c033e5' User entered 'Yes (Y)'	System	31 Aug 2020 01:26:54
	System	31 Aug 2020 01:26:54

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-30T20:26:45', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '194b0995-c754-47b6-ad6e-0c6744c033e5' User entered '97.2'	System	31 Aug 2020 01:26:54
	System	31 Aug 2020 01:26:54

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:26:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '194b0995-c754-47b6-ad6e-0c6744c033e5' User entered 'No (N)'	System	31 Aug 2020 01:26:54
	System	31 Aug 2020 01:26:54

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:26:53', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '194b0995-c754-47b6-ad6e-0c6744c033e5' User entered '30 Aug 2020 20:26'	System	31 Aug 2020 01:26:54
	System	31 Aug 2020 01:26:54

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:21:27', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'dfb626c8-361a-4148-a5c1-69c95ec360d5' User entered 'None (1)'	System	24 Aug 2020 19:22:17
	System	24 Aug 2020 19:22:17

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T14:21:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'dfb626c8-361a-4148-a5c1-69c95ec360d5' User entered 'No (N)'	System	24 Aug 2020 19:22:17
	System	24 Aug 2020 19:22:17

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T14:22:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'dfb626c8-361a-4148-a5c1-69c95ec360d5' User entered 'No (N)'	System	24 Aug 2020 19:22:17
	System	24 Aug 2020 19:22:17

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T14:22:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'dfb626c8-361a-4148-a5c1-69c95ec360d5' User entered 'None (1)'	System	24 Aug 2020 19:22:17
	System	24 Aug 2020 19:22:17

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T14:22:14', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'dfb626c8-361a-4148-a5c1-69c95ec360d5' User entered '24 Aug 2020 14:22'	System	24 Aug 2020 19:22:17
	System	24 Aug 2020 19:22:17

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 14:07'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 16:37'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T21:10:24', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ac58aa00-93df-40ae-a2ba-9aad8aef6adb' User entered 'None (1)'	System	25 Aug 2020 02:10:47
	System	25 Aug 2020 02:10:47

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:10:28', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ac58aa00-93df-40ae-a2ba-9aad8aef6adb' User entered 'No (N)'	System	25 Aug 2020 02:10:47
	System	25 Aug 2020 02:10:47

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:10:31', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ac58aa00-93df-40ae-a2ba-9aad8aef6adb' User entered 'No (N)'	System	25 Aug 2020 02:10:47
	System	25 Aug 2020 02:10:47

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T21:10:37', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ac58aa00-93df-40ae-a2ba-9aad8aef6adb' User entered 'None (1)'	System	25 Aug 2020 02:10:47
	System	25 Aug 2020 02:10:47

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:10:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ac58aa00-93df-40ae-a2ba-9aad8aef6adb' User entered '24 Aug 2020 21:10'	System	25 Aug 2020 02:10:47
	System	25 Aug 2020 02:10:47

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 17:32'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 2'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-25T21:04:59', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'eac28938-a411-434d-b881-3041c6a854db' User entered 'None (1)'	System	26 Aug 2020 02:05:21
	System	26 Aug 2020 02:05:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:02', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'eac28938-a411-434d-b881-3041c6a854db' User entered 'No (N)'	System	26 Aug 2020 02:05:21
	System	26 Aug 2020 02:05:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:05', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'eac28938-a411-434d-b881-3041c6a854db' User entered 'No (N)'	System	26 Aug 2020 02:05:21
	System	26 Aug 2020 02:05:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-25T21:05:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'eac28938-a411-434d-b881-3041c6a854db' User entered 'None (1)'	System	26 Aug 2020 02:05:21
	System	26 Aug 2020 02:05:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'eac28938-a411-434d-b881-3041c6a854db' User entered '25 Aug 2020 21:05'	System	26 Aug 2020 02:05:21
	System	26 Aug 2020 02:05:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 3'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:04:12', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff71dc85-d873-43e2-819a-115fc4b6bd60'	System	27 Aug 2020 03:04:29
User entered 'None (1)'	System	27 Aug 2020 03:04:29

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-26T22:04:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff71dc85-d873-43e2-819a-115fc4b6bd60' User entered 'No (N)'	System	27 Aug 2020 03:04:29
	System	27 Aug 2020 03:04:29

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:04:18', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff71dc85-d873-43e2-819a-115fc4b6bd60' User entered 'No (N)'	System	27 Aug 2020 03:04:29
	System	27 Aug 2020 03:04:29

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:04:21', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff71dc85-d873-43e2-819a-115fc4b6bd60'	System	27 Aug 2020 03:04:29
User entered 'None (1)'	System	27 Aug 2020 03:04:29

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-26T22:04:25', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff71dc85-d873-43e2-819a-115fc4b6bd60' User entered '26 Aug 2020 22:04'	System	27 Aug 2020 03:04:29
	System	27 Aug 2020 03:04:29

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 4'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-27T22:14:06', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '02763f56-3667-4022-a60f-6b16fcefdaba' User entered 'None (1)'	System	28 Aug 2020 03:14:21
	System	28 Aug 2020 03:14:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-27T22:14:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '02763f56-3667-4022-a60f-6b16fcefdeba' User entered 'No (N)'	System	28 Aug 2020 03:14:21
	System	28 Aug 2020 03:14:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-27T22:14:12', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '02763f56-3667-4022-a60f-6b16fcefdeba' User entered 'No (N)'	System	28 Aug 2020 03:14:21
	System	28 Aug 2020 03:14:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-27T22:14:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '02763f56-3667-4022-a60f-6b16fcefdaba' User entered 'None (1)'	System	28 Aug 2020 03:14:21
	System	28 Aug 2020 03:14:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-27T22:14:19', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '02763f56-3667-4022-a60f-6b16fcefdeba' User entered '27 Aug 2020 22:14'	System	28 Aug 2020 03:14:21
	System	28 Aug 2020 03:14:21

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 5'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:45:17', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '322b4eb2-bb7b-4268-8ee9-f28a471af8f4' User entered 'None (1)'	System	29 Aug 2020 01:45:35
	System	29 Aug 2020 01:45:35

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-28T20:45:21', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '322b4eb2-bb7b-4268-8ee9-f28a471af8f4' User entered 'No (N)'	System	29 Aug 2020 01:45:35
	System	29 Aug 2020 01:45:35

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:45:24', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '322b4eb2-bb7b-4268-8ee9-f28a471af8f4' User entered 'No (N)'	System	29 Aug 2020 01:45:35
	System	29 Aug 2020 01:45:35

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:45:28', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '322b4eb2-bb7b-4268-8ee9-f28a471af8f4' User entered 'None (1)'	System	29 Aug 2020 01:45:35
	System	29 Aug 2020 01:45:35

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:45:32', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '322b4eb2-bb7b-4268-8ee9-f28a471af8f4' User entered '28 Aug 2020 20:45'	System	29 Aug 2020 01:45:35
	System	29 Aug 2020 01:45:35

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 6'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:30', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3cd751b4-abc5-4c97-814a-6f543e53aa54' User entered 'None (1)'	System	30 Aug 2020 04:59:46
	System	30 Aug 2020 04:59:46

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:33', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3cd751b4-abc5-4c97-814a-6f543e53aa54' User entered 'No (N)'	System	30 Aug 2020 04:59:46
	System	30 Aug 2020 04:59:46

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3cd751b4-abc5-4c97-814a-6f543e53aa54' User entered 'No (N)'	System	30 Aug 2020 04:59:46
	System	30 Aug 2020 04:59:46

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:39', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3cd751b4-abc5-4c97-814a-6f543e53aa54' User entered 'None (1)'	System	30 Aug 2020 04:59:46
	System	30 Aug 2020 04:59:46

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:45', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3cd751b4-abc5-4c97-814a-6f543e53aa54' User entered '29 Aug 2020 23:59'	System	30 Aug 2020 04:59:46
	System	30 Aug 2020 04:59:46

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 7'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-30T20:26:57', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '052830ff-12a9-4c6b-8c11-f7c15bdfefdb' User entered 'None (1)'	System	31 Aug 2020 01:27:13
	System	31 Aug 2020 01:27:13

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '052830ff-12a9-4c6b-8c11-f7c15bdfefdb' User entered 'No (N)'	System	31 Aug 2020 01:27:13
	System	31 Aug 2020 01:27:13

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:03', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '052830ff-12a9-4c6b-8c11-f7c15bdfefdb' User entered 'No (N)'	System	31 Aug 2020 01:27:13
	System	31 Aug 2020 01:27:13

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-30T20:27:06', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '052830ff-12a9-4c6b-8c11-f7c15bdfefdb' User entered 'None (1)'	System	31 Aug 2020 01:27:13
	System	31 Aug 2020 01:27:13

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-30T20:27:10', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '052830ff-12a9-4c6b-8c11-f7c15bdfefdb' User entered '30 Aug 2020 20:27'	System	31 Aug 2020 01:27:13
	System	31 Aug 2020 01:27:13

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:22:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '646ce306-1fd0-4804-9207-80c5edf857a6' User entered 'None (0)'	System	24 Aug 2020 19:24:20
	System	24 Aug 2020 19:24:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:22:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '646ce306-1fd0-4804-9207-80c5edf857a6' User entered 'None (0)'	System	24 Aug 2020 19:24:20
	System	24 Aug 2020 19:24:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:22:53', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '646ce306-1fd0-4804-9207-80c5edf857a6' User entered 'None (0)'	System	24 Aug 2020 19:24:20
	System	24 Aug 2020 19:24:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:22:59', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '646ce306-1fd0-4804-9207-80c5edf857a6' User entered 'None (0)'	System	24 Aug 2020 19:24:20
	System	24 Aug 2020 19:24:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:23:02', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '646ce306-1fd0-4804-9207-80c5edf857a6' User entered 'None (0)'	System	24 Aug 2020 19:24:20
	System	24 Aug 2020 19:24:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:23:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '646ce306-1fd0-4804-9207-80c5edf857a6' User entered 'None (0)'	System	24 Aug 2020 19:24:20
	System	24 Aug 2020 19:24:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:23:17', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '646ce306-1fd0-4804-9207-80c5edf857a6' User entered 'No (N)'	System	24 Aug 2020 19:24:20
	System	24 Aug 2020 19:24:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-24T14:24:18', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '646ce306-1fd0-4804-9207-80c5edf857a6' User entered '24 Aug 2020 14:24'	System	24 Aug 2020 19:24:20
	System	24 Aug 2020 19:24:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 14:07'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 16:37'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:10:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '94519385-f84f-4a58-a36d-153858637518' User entered 'None (0)'	System	25 Aug 2020 02:11:23
	System	25 Aug 2020 02:11:23

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:10:55', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '94519385-f84f-4a58-a36d-153858637518' User entered 'None (0)'	System	25 Aug 2020 02:11:23
	System	25 Aug 2020 02:11:23

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:10:59', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '94519385-f84f-4a58-a36d-153858637518' User entered 'None (0)'	System	25 Aug 2020 02:11:23
	System	25 Aug 2020 02:11:23

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:11:02', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '94519385-f84f-4a58-a36d-153858637518' User entered 'None (0)'	System	25 Aug 2020 02:11:23
	System	25 Aug 2020 02:11:23

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:11:05', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '94519385-f84f-4a58-a36d-153858637518' User entered 'None (0)'	System	25 Aug 2020 02:11:23
	System	25 Aug 2020 02:11:23

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:11:08', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '94519385-f84f-4a58-a36d-153858637518' User entered 'None (0)'	System	25 Aug 2020 02:11:23
	System	25 Aug 2020 02:11:23

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:11:13', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '94519385-f84f-4a58-a36d-153858637518' User entered 'No (N)'	System	25 Aug 2020 02:11:23
	System	25 Aug 2020 02:11:23

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-24T21:11:20', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '94519385-f84f-4a58-a36d-153858637518' User entered '24 Aug 2020 21:11'	System	25 Aug 2020 02:11:23
	System	25 Aug 2020 02:11:23

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Aug 2020 17:32'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 2'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:23', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5a2e7301-7faf-4e5e-a75f-8246d2930e9d' User entered 'None (0)'	System	26 Aug 2020 02:05:58
	System	26 Aug 2020 02:05:58

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:25', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5a2e7301-7faf-4e5e-a75f-8246d2930e9d' User entered 'None (0)'	System	26 Aug 2020 02:05:58
	System	26 Aug 2020 02:05:58

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-25T21:05:31', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5a2e7301-7faf-4e5e-a75f-8246d2930e9d' User entered 'None (0)'	System	26 Aug 2020 02:05:58
	System	26 Aug 2020 02:05:58

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:34', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5a2e7301-7faf-4e5e-a75f-8246d2930e9d' User entered 'None (0)'	System	26 Aug 2020 02:05:58
	System	26 Aug 2020 02:05:58

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5a2e7301-7faf-4e5e-a75f-8246d2930e9d' User entered 'None (0)'	System	26 Aug 2020 02:05:58
	System	26 Aug 2020 02:05:58

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-25T21:05:38', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5a2e7301-7faf-4e5e-a75f-8246d2930e9d' User entered 'None (0)'	System	26 Aug 2020 02:05:58
	System	26 Aug 2020 02:05:58

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:43', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5a2e7301-7faf-4e5e-a75f-8246d2930e9d' User entered 'No (N)'	System	26 Aug 2020 02:05:58
	System	26 Aug 2020 02:05:58

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-25T21:05:50', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5a2e7301-7faf-4e5e-a75f-8246d2930e9d' User entered '25 Aug 2020 21:05'	System	26 Aug 2020 02:05:58
	System	26 Aug 2020 02:05:58

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 3'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-26T22:04:30', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'abb62a7d-1394-433b-83b9-73ac98701737' User entered 'None (0)'	System	27 Aug 2020 03:04:55
	System	27 Aug 2020 03:04:55

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-26T22:04:32', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'abb62a7d-1394-433b-83b9-73ac98701737' User entered 'None (0)'	System	27 Aug 2020 03:04:55
	System	27 Aug 2020 03:04:55

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:04:35', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'abb62a7d-1394-433b-83b9-73ac98701737' User entered 'None (0)'	System	27 Aug 2020 03:04:55
	System	27 Aug 2020 03:04:55

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-26T22:04:37', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'abb62a7d-1394-433b-83b9-73ac98701737' User entered 'None (0)'	System	27 Aug 2020 03:04:55
	System	27 Aug 2020 03:04:55

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:04:39', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'abb62a7d-1394-433b-83b9-73ac98701737' User entered 'None (0)'	System	27 Aug 2020 03:04:55
	System	27 Aug 2020 03:04:55

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-26T22:04:42', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'abb62a7d-1394-433b-83b9-73ac98701737' User entered 'None (0)'	System	27 Aug 2020 03:04:55
	System	27 Aug 2020 03:04:55

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-26T22:04:48', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'abb62a7d-1394-433b-83b9-73ac98701737'	System	27 Aug 2020 03:04:55
User entered 'No (N)'	System	27 Aug 2020 03:04:55

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-26T22:04:53', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'abb62a7d-1394-433b-83b9-73ac98701737' User entered '26 Aug 2020 22:04'	System	27 Aug 2020 03:04:55
	System	27 Aug 2020 03:04:55

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 4'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:23', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '684c45da-db41-433d-9edd-b5c7dfa618eb' User entered 'None (0)'	System	28 Aug 2020 03:14:48
	System	28 Aug 2020 03:14:48

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:25', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '684c45da-db41-433d-9edd-b5c7dfa618eb' User entered 'None (0)'	System	28 Aug 2020 03:14:48
	System	28 Aug 2020 03:14:48

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:28', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '684c45da-db41-433d-9edd-b5c7dfa618eb' User entered 'None (0)'	System	28 Aug 2020 03:14:48
	System	28 Aug 2020 03:14:48

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:30', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '684c45da-db41-433d-9edd-b5c7dfa618eb' User entered 'None (0)'	System	28 Aug 2020 03:14:48
	System	28 Aug 2020 03:14:48

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:33', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '684c45da-db41-433d-9edd-b5c7dfa618eb' User entered 'None (0)'	System	28 Aug 2020 03:14:48
	System	28 Aug 2020 03:14:48

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:35', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '684c45da-db41-433d-9edd-b5c7dfa618eb' User entered 'None (0)'	System	28 Aug 2020 03:14:48
	System	28 Aug 2020 03:14:48

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '684c45da-db41-433d-9edd-b5c7dfa618eb' User entered 'No (N)'	System	28 Aug 2020 03:14:48
	System	28 Aug 2020 03:14:48

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-27T22:14:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '684c45da-db41-433d-9edd-b5c7dfa618eb' User entered '27 Aug 2020 22:14'	System	28 Aug 2020 03:14:48
	System	28 Aug 2020 03:14:48

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 5'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-28T20:45:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f6b7596e-477f-470e-b01c-b3d741241cfd' User entered 'None (0)'	System	29 Aug 2020 01:46:01
	System	29 Aug 2020 01:46:01

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-28T20:45:38', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f6b7596e-477f-470e-b01c-b3d741241cfd' User entered 'None (0)'	System	29 Aug 2020 01:46:01
	System	29 Aug 2020 01:46:01

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:45:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f6b7596e-477f-470e-b01c-b3d741241cfd' User entered 'None (0)'	System	29 Aug 2020 01:46:01
	System	29 Aug 2020 01:46:01

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-28T20:45:43', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f6b7596e-477f-470e-b01c-b3d741241cfd' User entered 'None (0)'	System	29 Aug 2020 01:46:01
	System	29 Aug 2020 01:46:01

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:45:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f6b7596e-477f-470e-b01c-b3d741241cfd' User entered 'None (0)'	System	29 Aug 2020 01:46:01
	System	29 Aug 2020 01:46:01

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-28T20:45:48', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f6b7596e-477f-470e-b01c-b3d741241cfd' User entered 'None (0)'	System	29 Aug 2020 01:46:01
	System	29 Aug 2020 01:46:01

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-28T20:45:53', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f6b7596e-477f-470e-b01c-b3d741241cfd' User entered 'No (N)'	System	29 Aug 2020 01:46:01
	System	29 Aug 2020 01:46:01

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-28T20:45:59', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f6b7596e-477f-470e-b01c-b3d741241cfd' User entered '28 Aug 2020 20:45'	System	29 Aug 2020 01:46:01
	System	29 Aug 2020 01:46:01

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 6'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-29T23:59:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff7ac371-759c-4e6a-8842-f40a5df6ee78' User entered 'None (0)'	System	30 Aug 2020 05:00:09
	System	30 Aug 2020 05:00:09

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:51', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff7ac371-759c-4e6a-8842-f40a5df6ee78' User entered 'None (0)'	System	30 Aug 2020 05:00:09
	System	30 Aug 2020 05:00:09

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-29T23:59:53', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff7ac371-759c-4e6a-8842-f40a5df6ee78' User entered 'None (0)'	System	30 Aug 2020 05:00:09
	System	30 Aug 2020 05:00:09

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-29T23:59:55', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff7ac371-759c-4e6a-8842-f40a5df6ee78' User entered 'None (0)'	System	30 Aug 2020 05:00:09
	System	30 Aug 2020 05:00:09

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-29T23:59:57', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff7ac371-759c-4e6a-8842-f40a5df6ee78' User entered 'None (0)'	System	30 Aug 2020 05:00:09
	System	30 Aug 2020 05:00:09

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-29T23:59:59', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff7ac371-759c-4e6a-8842-f40a5df6ee78' User entered 'None (0)'	System	30 Aug 2020 05:00:09
	System	30 Aug 2020 05:00:09

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T00:00:03', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff7ac371-759c-4e6a-8842-f40a5df6ee78' User entered 'No (N)'	System	30 Aug 2020 05:00:09
	System	30 Aug 2020 05:00:09

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T00:00:05', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ff7ac371-759c-4e6a-8842-f40a5df6ee78' User entered '30 Aug 2020 00:00'	System	30 Aug 2020 05:00:09
	System	30 Aug 2020 05:00:09

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 7'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:14', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'fa1ad1d7-4442-4bbe-9076-dadc9656d12e' User entered 'None (0)'	System	31 Aug 2020 01:27:38
	System	31 Aug 2020 01:27:38

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:17', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'fa1ad1d7-4442-4bbe-9076-dadc9656d12e' User entered 'None (0)'	System	31 Aug 2020 01:27:38
	System	31 Aug 2020 01:27:38

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:19', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'fa1ad1d7-4442-4bbe-9076-dadc9656d12e' User entered 'None (0)'	System	31 Aug 2020 01:27:38
	System	31 Aug 2020 01:27:38

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:22', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'fa1ad1d7-4442-4bbe-9076-dadc9656d12e' User entered 'None (0)'	System	31 Aug 2020 01:27:38
	System	31 Aug 2020 01:27:38

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:24', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'fa1ad1d7-4442-4bbe-9076-dadc9656d12e' User entered 'None (0)'	System	31 Aug 2020 01:27:38
	System	31 Aug 2020 01:27:38

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:26', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'fa1ad1d7-4442-4bbe-9076-dadc9656d12e' User entered 'None (0)'	System	31 Aug 2020 01:27:38
	System	31 Aug 2020 01:27:38

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-08-30T20:27:31', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'fa1ad1d7-4442-4bbe-9076-dadc9656d12e' User entered 'No (N)'	System	31 Aug 2020 01:27:38
	System	31 Aug 2020 01:27:38

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-08-30T20:27:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'fa1ad1d7-4442-4bbe-9076-dadc9656d12e' User entered '30 Aug 2020 20:27'	System	31 Aug 2020 01:27:38
	System	31 Aug 2020 01:27:38

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 18:47:20

US3852015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:56:02

US3852015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '1 Sep 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:56:02

US3852015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:56:02

US3852015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:56:02

US3852015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:56:10

US3852015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	01 Sep 2020 14:56:10

US3852015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	08 Sep 2020 19:38:58

US3852015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '8 Sep 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	08 Sep 2020 19:38:58

US3852015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	08 Sep 2020 19:38:58

US3852015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	08 Sep 2020 19:38:58

US3852015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	08 Sep 2020 19:39:03

US3852015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	08 Sep 2020 19:39:03

US3852015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	14 Sep 2020 17:20:49

US3852015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '14 Sep 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	14 Sep 2020 17:20:49

US3852015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	14 Sep 2020 17:20:49

US3852015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	14 Sep 2020 17:20:49

US3852015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	14 Sep 2020 17:20:55

US3852015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	14 Sep 2020 17:20:55

US3852015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	21 Sep 2020 14:21:23

US3852015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '21 Sep 2020'	Jessica Bartlett (b) (4)	21 Sep 2020 14:21:23

US3852015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Clinic (Clinic)'	Jessica Bartlett (b) (4)	21 Sep 2020 14:21:23

US3852015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'VISIT2'	System	21 Sep 2020 14:21:23

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '09:15'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '21 Sep 2020 09:15'	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Oct 2020 09:17:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Oct 2020 09:17:29
User entered '97.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 09:17:29
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 09:16:40
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:17:29
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Temporal' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:17:29
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Oct 2020 09:17:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Oct 2020 09:17:29
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 09:17:29
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 09:16:40
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'bpm'	System	16 Oct 2020 09:17:29
User entered empty.	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Oct 2020 09:17:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Oct 2020 09:17:29
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 09:17:29
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 09:16:40
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'breaths/min'	System	16 Oct 2020 09:17:29
User entered empty.	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Oct 2020 09:17:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Oct 2020 09:17:29
User entered '111' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 09:17:29
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 09:16:40
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	16 Oct 2020 09:17:29
User entered empty.	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Oct 2020 09:17:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Oct 2020 09:17:29
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 09:17:29
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 09:16:40
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	16 Oct 2020 09:17:29
User entered empty.	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '10:39'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '21 Sep 2020 10:39'	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Oct 2020 09:18:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Oct 2020 09:18:21
User entered '98.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 09:18:21
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 09:16:40
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:18:21
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Temporal' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:18:21
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Oct 2020 09:18:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Oct 2020 09:18:21
User entered '57' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 09:18:21
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 09:16:40
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'bpm'	System	16 Oct 2020 09:18:21
User entered empty.	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.'	(b) (4)	16 Oct 2020 09:18:21
(Site from System).	System	16 Oct 2020 09:18:21
Query 'Data is required. Please provide.' answered by System		16 Oct 2020 09:18:21
data change (Site from System).		
User entered '18' reason for change: Data Entry	(b) (4), (b) (6)	16 Oct 2020 09:18:21
Error		
User opened query 'Data is required. Please provide.'	System	16 Oct 2020 09:16:40
(Site from System).		
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'breaths/min'	System	16 Oct 2020 09:18:21
User entered empty.	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Oct 2020 09:18:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Oct 2020 09:18:21
User entered '115' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 09:18:21
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 09:16:40
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	16 Oct 2020 09:18:21
User entered empty.	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Data is required. Please provide.'	(b) (4)	16 Oct 2020 09:18:21
(Site from System).	System	16 Oct 2020 09:18:21
Query 'Data is required. Please provide.' answered by System		16 Oct 2020 09:18:21
data change (Site from System).		
User entered '72' reason for change: Data Entry	(b) (4), (b) (6)	16 Oct 2020 09:18:21
Error		
User opened query 'Data is required. Please provide.'	System	16 Oct 2020 09:16:40
(Site from System).		
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	16 Oct 2020 09:18:21
User entered empty.	System	16 Oct 2020 09:16:40

US3852015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:18:31

US3852015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:18:31

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query ' Per Immuno Lab Recon: Please complete Immunogenicity and Central Lab forms ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 09:08:16
Query ' Per Immuno Lab Recon: Please complete Immunogenicity and Central Lab forms ' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:20:36
User opened query ' Per Immuno Lab Recon: Please complete Immunogenicity and Central Lab forms ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 02:07:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

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 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '10:04'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '21 Sep 2020 10:04'	System	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'ONCE'	System	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 15:21:29

US3852015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:19:15

US3852015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:19:15

US3852015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '9:33'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:19:15

US3852015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '21 Sep 2020 9:33'	System	16 Oct 2020 09:19:15

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:03:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '9:30'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '21 Sep 2020 9:30'	System	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered empty.	System	16 Oct 2020 09:19:42

US3852015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	06 Oct 2020 16:18:33

US3852015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	06 Oct 2020 16:18:33

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:42:48', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'df657177-1373-41ff-a5cf-9f551677358e' User entered 'Yes (Y)'	System	21 Sep 2020 15:43:37
	System	21 Sep 2020 15:43:37

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T10:42:54', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'df657177-1373-41ff-a5cf-9f551677358e' User entered '98.4'	System	21 Sep 2020 15:43:37
	System	21 Sep 2020 15:43:37

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:43:03', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'df657177-1373-41ff-a5cf-9f551677358e' User entered 'No (N)'	System	21 Sep 2020 15:43:37
	System	21 Sep 2020 15:43:37

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:43:30', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'df657177-1373-41ff-a5cf-9f551677358e' User entered '21 Sep 2020 10:43'	System	21 Sep 2020 15:43:37
	System	21 Sep 2020 15:43:37

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 10:24'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 12:54'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T20:26:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'debca7c-cf01-4610-a468-b8f6adfc0b83' User entered 'Yes (Y)'	System	22 Sep 2020 01:27:09
	System	22 Sep 2020 01:27:09

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T20:26:55', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'debcab7c-cf01-4610-a468-b8f6adfc0b83' User entered '97.5'	System	22 Sep 2020 01:27:09
	System	22 Sep 2020 01:27:09

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:27:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'debcab7c-cf01-4610-a468-b8f6adfc0b83' User entered 'No (N)'	System	22 Sep 2020 01:27:09
	System	22 Sep 2020 01:27:09

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T20:27:07', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'debca7c-cf01-4610-a468-b8f6adfc0b83' User entered '21 Sep 2020 20:27'	System	22 Sep 2020 01:27:09
	System	22 Sep 2020 01:27:09

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 13:49'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 2'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:25', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '855db7d1-05c6-417c-b429-b6d51adb4ffc' User entered 'Yes (Y)'	System	23 Sep 2020 01:00:39
	System	23 Sep 2020 01:00:39

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:29', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '855db7d1-05c6-417c-b429-b6d51adb4ffc' User entered '98.4'	System	23 Sep 2020 01:00:39
	System	23 Sep 2020 01:00:39

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:32', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '855db7d1-05c6-417c-b429-b6d51adb4ffc' User entered 'No (N)'	System	23 Sep 2020 01:00:39
	System	23 Sep 2020 01:00:39

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:35', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '855db7d1-05c6-417c-b429-b6d51adb4ffc' User entered '22 Sep 2020 20:00'	System	23 Sep 2020 01:00:39
	System	23 Sep 2020 01:00:39

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 3'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:07', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '2b6a8f5d-bb15-4ff7-b62e-92c420d67c38'	System	24 Sep 2020 00:52:27
User entered 'Yes (Y)'	System	24 Sep 2020 00:52:27

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:12', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '2b6a8f5d-bb15-4ff7-b62e-92c420d67c38' User entered '97.5'	System	24 Sep 2020 00:52:27
	System	24 Sep 2020 00:52:27

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:17', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '2b6a8f5d-bb15-4ff7-b62e-92c420d67c38'	System	24 Sep 2020 00:52:27
User entered 'No (N)'	System	24 Sep 2020 00:52:27

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:22', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '2b6a8f5d-bb15-4ff7-b62e-92c420d67c38'	System	24 Sep 2020 00:52:27
User entered '23 Sep 2020 19:52'	System	24 Sep 2020 00:52:27

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 4'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T17:59:12', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b96c1faf-2a55-4b75-9a77-99ee11e62f3f' User entered 'Yes (Y)'	System	24 Sep 2020 22:59:27
	System	24 Sep 2020 22:59:27

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T17:59:18', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b96c1faf-2a55-4b75-9a77-99ee11e62f3f' User entered '97.5'	System	24 Sep 2020 22:59:27
	System	24 Sep 2020 22:59:27

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T17:59:21', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b96c1faf-2a55-4b75-9a77-99ee11e62f3f' User entered 'No (N)'	System	24 Sep 2020 22:59:27
	System	24 Sep 2020 22:59:27

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T17:59:25', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b96c1faf-2a55-4b75-9a77-99ee11e62f3f' User entered '24 Sep 2020 17:59'	System	24 Sep 2020 22:59:27
	System	24 Sep 2020 22:59:27

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 5'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:26:22', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ea43b2c4-df70-4578-8d16-46f278c2875b' User entered 'Yes (Y)'	System	26 Sep 2020 01:26:44
	System	26 Sep 2020 01:26:44

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-25T20:26:30', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ea43b2c4-df70-4578-8d16-46f278c2875b' User entered '97.5'	System	26 Sep 2020 01:26:44
	System	26 Sep 2020 01:26:44

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:26:34', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ea43b2c4-df70-4578-8d16-46f278c2875b' User entered 'No (N)'	System	26 Sep 2020 01:26:44
	System	26 Sep 2020 01:26:44

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:26:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ea43b2c4-df70-4578-8d16-46f278c2875b' User entered '25 Sep 2020 20:26'	System	26 Sep 2020 01:26:44
	System	26 Sep 2020 01:26:44

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 6'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-26T20:00:24', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '982f7591-f8bf-40d8-9631-dd48b9e31186' User entered 'Yes (Y)'	System	27 Sep 2020 01:00:56
	System	27 Sep 2020 01:00:56

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:00:31', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '982f7591-f8bf-40d8-9631-dd48b9e31186' User entered '97.5'	System	27 Sep 2020 01:00:56
	System	27 Sep 2020 01:00:56

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-26T20:00:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '982f7591-f8bf-40d8-9631-dd48b9e31186' User entered 'No (N)'	System	27 Sep 2020 01:00:56
	System	27 Sep 2020 01:00:56

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:00:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '982f7591-f8bf-40d8-9631-dd48b9e31186' User entered '26 Sep 2020 20:00'	System	27 Sep 2020 01:00:56
	System	27 Sep 2020 01:00:56

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 7'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:27:28', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f727a701-a726-4c30-b1f1-8aaf44d9f741' User entered 'Yes (Y)'	System	28 Sep 2020 01:27:45
	System	28 Sep 2020 01:27:45

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:27:32', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f727a701-a726-4c30-b1f1-8aaf44d9f741' User entered '98.1'	System	28 Sep 2020 01:27:45
	System	28 Sep 2020 01:27:45

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:27:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f727a701-a726-4c30-b1f1-8aaf44d9f741' User entered 'No (N)'	System	28 Sep 2020 01:27:45
	System	28 Sep 2020 01:27:45

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:27:41', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f727a701-a726-4c30-b1f1-8aaf44d9f741' User entered '27 Sep 2020 20:27'	System	28 Sep 2020 01:27:45
	System	28 Sep 2020 01:27:45

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:44:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7651e015-62f4-4ea3-90cf-78d4ffa19ea6' User entered 'None (1)'	System	21 Sep 2020 15:45:53
	System	21 Sep 2020 15:45:53

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:45:18', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7651e015-62f4-4ea3-90cf-78d4ffa19ea6' User entered 'No (N)'	System	21 Sep 2020 15:45:53
	System	21 Sep 2020 15:45:53

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T10:45:22', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7651e015-62f4-4ea3-90cf-78d4ffa19ea6' User entered 'No (N)'	System	21 Sep 2020 15:45:53
	System	21 Sep 2020 15:45:53

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:45:26', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7651e015-62f4-4ea3-90cf-78d4ffa19ea6' User entered 'None (1)'	System	21 Sep 2020 15:45:53
	System	21 Sep 2020 15:45:53

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:45:48', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7651e015-62f4-4ea3-90cf-78d4ffa19ea6' User entered '21 Sep 2020 10:45'	System	21 Sep 2020 15:45:53
	System	21 Sep 2020 15:45:53

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 10:24'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 12:54'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:27:26', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f8aaca4-bd6d-4cee-8e9d-2c7017f01a68' User entered 'None (1)'	System	22 Sep 2020 01:27:42
	System	22 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T20:27:29', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f8aacao4-bd6d-4cee-8e9d-2c7017f01a68'	System	22 Sep 2020 01:27:42
User entered 'No (N)'	System	22 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T20:27:32', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f8aaca4-bd6d-4cee-8e9d-2c7017f01a68' User entered 'No (N)'	System	22 Sep 2020 01:27:42
	System	22 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T20:27:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f8aaca4-bd6d-4cee-8e9d-2c7017f01a68'	System	22 Sep 2020 01:27:42
User entered 'None (1)'	System	22 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T20:27:39', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f8aacao4-bd6d-4cee-8e9d-2c7017f01a68'	System	22 Sep 2020 01:27:42
User entered '21 Sep 2020 20:27'	System	22 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 13:49'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 2'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:39', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4fc2b6bd-353d-433c-a8e0-d9af8a7bda73'	System	23 Sep 2020 01:00:55
User entered 'None (1)'	System	23 Sep 2020 01:00:55

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:42', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4fc2b6bd-353d-433c-a8e0-d9af8a7bda73' User entered 'No (N)'	System	23 Sep 2020 01:00:55
	System	23 Sep 2020 01:00:55

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:44', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4fc2b6bd-353d-433c-a8e0-d9af8a7bda73' User entered 'No (N)'	System	23 Sep 2020 01:00:55
	System	23 Sep 2020 01:00:55

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:47', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4fc2b6bd-353d-433c-a8e0-d9af8a7bda73'	System	23 Sep 2020 01:00:55
User entered 'None (1)'	System	23 Sep 2020 01:00:55

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4fc2b6bd-353d-433c-a8e0-d9af8a7bda73' User entered '22 Sep 2020 20:00'	System	23 Sep 2020 01:00:55
	System	23 Sep 2020 01:00:55

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 3'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:27', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5bd6c6c4-8846-4170-a696-f9f86b70842f' User entered 'None (1)'	System	24 Sep 2020 00:52:42
	System	24 Sep 2020 00:52:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-23T19:52:31', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5bd6c6c4-8846-4170-a696-f9f86b70842f' User entered 'No (N)'	System	24 Sep 2020 00:52:42
	System	24 Sep 2020 00:52:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:33', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5bd6c6c4-8846-4170-a696-f9f86b70842f' User entered 'No (N)'	System	24 Sep 2020 00:52:42
	System	24 Sep 2020 00:52:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:37', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5bd6c6c4-8846-4170-a696-f9f86b70842f' User entered 'None (1)'	System	24 Sep 2020 00:52:42
	System	24 Sep 2020 00:52:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-23T19:52:41', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '5bd6c6c4-8846-4170-a696-f9f86b70842f' User entered '23 Sep 2020 19:52'	System	24 Sep 2020 00:52:42
	System	24 Sep 2020 00:52:42

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 4'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T17:59:43', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c0d6b04f-5ea1-4aa7-bf9f-40173bc093f1' User entered 'None (1)'	System	24 Sep 2020 23:00:30
	System	24 Sep 2020 23:00:30

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T17:59:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c0d6b04f-5ea1-4aa7-bf9f-40173bc093f1' User entered 'No (N)'	System	24 Sep 2020 23:00:30
	System	24 Sep 2020 23:00:30

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-24T17:59:53', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c0d6b04f-5ea1-4aa7-bf9f-40173bc093f1' User entered 'No (N)'	System	24 Sep 2020 23:00:30
	System	24 Sep 2020 23:00:30

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-24T18:00:03', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c0d6b04f-5ea1-4aa7-bf9f-40173bc093f1' User entered 'None (1)'	System	24 Sep 2020 23:00:30
	System	24 Sep 2020 23:00:30

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-24T18:00:28', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c0d6b04f-5ea1-4aa7-bf9f-40173bc093f1' User entered '24 Sep 2020 18:00'	System	24 Sep 2020 23:00:30
	System	24 Sep 2020 23:00:30

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 5'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:26:47', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7f2e1276-c61e-4c66-a643-b633d4b9ac05' User entered 'None (1)'	System	26 Sep 2020 01:27:12
	System	26 Sep 2020 01:27:12

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:26:55', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7f2e1276-c61e-4c66-a643-b633d4b9ac05' User entered 'No (N)'	System	26 Sep 2020 01:27:12
	System	26 Sep 2020 01:27:12

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:26:59', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7f2e1276-c61e-4c66-a643-b633d4b9ac05' User entered 'No (N)'	System	26 Sep 2020 01:27:12
	System	26 Sep 2020 01:27:12

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:27:03', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7f2e1276-c61e-4c66-a643-b633d4b9ac05' User entered 'None (1)'	System	26 Sep 2020 01:27:12
	System	26 Sep 2020 01:27:12

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:27:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7f2e1276-c61e-4c66-a643-b633d4b9ac05' User entered '25 Sep 2020 20:27'	System	26 Sep 2020 01:27:12
	System	26 Sep 2020 01:27:12

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 6'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-26T20:01:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7d4f1171-1960-468b-9981-94fe76962a4d' User entered 'None (1)'	System	27 Sep 2020 01:02:10
	System	27 Sep 2020 01:02:10

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-26T20:01:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7d4f1171-1960-468b-9981-94fe76962a4d' User entered 'No (N)'	System	27 Sep 2020 01:02:10
	System	27 Sep 2020 01:02:10

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-26T20:01:54', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7d4f1171-1960-468b-9981-94fe76962a4d' User entered 'No (N)'	System	27 Sep 2020 01:02:10
	System	27 Sep 2020 01:02:10

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:01:57', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7d4f1171-1960-468b-9981-94fe76962a4d' User entered 'None (1)'	System	27 Sep 2020 01:02:10
	System	27 Sep 2020 01:02:10

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-26T20:02:04', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7d4f1171-1960-468b-9981-94fe76962a4d' User entered '26 Sep 2020 20:02'	System	27 Sep 2020 01:02:10
	System	27 Sep 2020 01:02:10

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 7'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:27:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '664e16f8-a1ee-4ff9-a045-6e40ef65edfd' User entered 'None (1)'	System	28 Sep 2020 01:28:07
	System	28 Sep 2020 01:28:07

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-27T20:27:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '664e16f8-a1ee-4ff9-a045-6e40ef65edfd' User entered 'No (N)'	System	28 Sep 2020 01:28:07
	System	28 Sep 2020 01:28:07

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:27:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '664e16f8-a1ee-4ff9-a045-6e40ef65edfd' User entered 'No (N)'	System	28 Sep 2020 01:28:07
	System	28 Sep 2020 01:28:07

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:27:58', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '664e16f8-a1ee-4ff9-a045-6e40ef65edfd' User entered 'None (1)'	System	28 Sep 2020 01:28:07
	System	28 Sep 2020 01:28:07

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:05', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '664e16f8-a1ee-4ff9-a045-6e40ef65edfd' User entered '27 Sep 2020 20:28'	System	28 Sep 2020 01:28:07
	System	28 Sep 2020 01:28:07

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T10:45:53', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '073cd1a7-0999-4f0a-b5d0-fbfd5480c191' User entered 'None (0)'	System	21 Sep 2020 15:46:47
	System	21 Sep 2020 15:46:47

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T10:45:57', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '073cd1a7-0999-4f0a-b5d0-fbfd5480c191' User entered 'None (0)'	System	21 Sep 2020 15:46:47
	System	21 Sep 2020 15:46:47

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:46:08', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '073cd1a7-0999-4f0a-b5d0-fbfd5480c191' User entered 'None (0)'	System	21 Sep 2020 15:46:47
	System	21 Sep 2020 15:46:47

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:46:11', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '073cd1a7-0999-4f0a-b5d0-fbfd5480c191' User entered 'None (0)'	System	21 Sep 2020 15:46:47
	System	21 Sep 2020 15:46:47

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:46:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '073cd1a7-0999-4f0a-b5d0-fbfd5480c191' User entered 'None (0)'	System	21 Sep 2020 15:46:47
	System	21 Sep 2020 15:46:47

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-21T10:46:20', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '073cd1a7-0999-4f0a-b5d0-fbfd5480c191' User entered 'None (0)'	System	21 Sep 2020 15:46:47
	System	21 Sep 2020 15:46:47

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:46:31', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '073cd1a7-0999-4f0a-b5d0-fbfd5480c191' User entered 'No (N)'	System	21 Sep 2020 15:46:47
	System	21 Sep 2020 15:46:47

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T10:46:44', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '073cd1a7-0999-4f0a-b5d0-fbfd5480c191' User entered '21 Sep 2020 10:46'	System	21 Sep 2020 15:46:47
	System	21 Sep 2020 15:46:47

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 10:24'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 12:54'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:27:44', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ee1163fa-2610-4605-b026-44cda3193711' User entered 'None (0)'	System	22 Sep 2020 01:28:18
	System	22 Sep 2020 01:28:18

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:27:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ee1163fa-2610-4605-b026-44cda3193711' User entered 'None (0)'	System	22 Sep 2020 01:28:18
	System	22 Sep 2020 01:28:18

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:27:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ee1163fa-2610-4605-b026-44cda3193711' User entered 'None (0)'	System	22 Sep 2020 01:28:18
	System	22 Sep 2020 01:28:18

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:28:01', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ee1163fa-2610-4605-b026-44cda3193711' User entered 'None (0)'	System	22 Sep 2020 01:28:18
	System	22 Sep 2020 01:28:18

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:28:04', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ee1163fa-2610-4605-b026-44cda3193711' User entered 'None (0)'	System	22 Sep 2020 01:28:18
	System	22 Sep 2020 01:28:18

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:28:06', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ee1163fa-2610-4605-b026-44cda3193711' User entered 'None (0)'	System	22 Sep 2020 01:28:18
	System	22 Sep 2020 01:28:18

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:28:10', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ee1163fa-2610-4605-b026-44cda3193711' User entered 'No (N)'	System	22 Sep 2020 01:28:18
	System	22 Sep 2020 01:28:18

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-21T20:28:14', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'ee1163fa-2610-4605-b026-44cda3193711' User entered '21 Sep 2020 20:28'	System	22 Sep 2020 01:28:18
	System	22 Sep 2020 01:28:18

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '21 Sep 2020 13:49'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 2'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:00:56', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7c2604e1-f85f-40dd-9a42-79e5a2fed057'	System	23 Sep 2020 01:01:26
User entered 'None (0)'	System	23 Sep 2020 01:01:26

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-22T20:00:58', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7c2604e1-f85f-40dd-9a42-79e5a2fed057' User entered 'None (0)'	System	23 Sep 2020 01:01:26
	System	23 Sep 2020 01:01:26

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-22T20:01:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7c2604e1-f85f-40dd-9a42-79e5a2fed057' User entered 'None (0)'	System	23 Sep 2020 01:01:26
	System	23 Sep 2020 01:01:26

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-22T20:01:03', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7c2604e1-f85f-40dd-9a42-79e5a2fed057' User entered 'None (0)'	System	23 Sep 2020 01:01:26
	System	23 Sep 2020 01:01:26

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-22T20:01:05', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7c2604e1-f85f-40dd-9a42-79e5a2fed057' User entered 'None (0)'	System	23 Sep 2020 01:01:26
	System	23 Sep 2020 01:01:26

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-22T20:01:07', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7c2604e1-f85f-40dd-9a42-79e5a2fed057' User entered 'None (0)'	System	23 Sep 2020 01:01:26
	System	23 Sep 2020 01:01:26

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-22T20:01:12', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7c2604e1-f85f-40dd-9a42-79e5a2fed057' User entered 'No (N)'	System	23 Sep 2020 01:01:26
	System	23 Sep 2020 01:01:26

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-22T20:01:20', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '7c2604e1-f85f-40dd-9a42-79e5a2fed057' User entered '22 Sep 2020 20:01'	System	23 Sep 2020 01:01:26
	System	23 Sep 2020 01:01:26

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 3'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '274422a0-34cc-47a0-a098-bae4df0905' User entered 'None (0)'	System	24 Sep 2020 00:53:12
	System	24 Sep 2020 00:53:12

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:48', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '274422a0-34cc-47a0-a098-bae4df0905' User entered 'None (0)'	System	24 Sep 2020 00:53:12
	System	24 Sep 2020 00:53:12

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:51', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '274422a0-34cc-47a0-a098-bae4df0905' User entered 'None (0)'	System	24 Sep 2020 00:53:12
	System	24 Sep 2020 00:53:12

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:54', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '274422a0-34cc-47a0-a098-bae4df0905' User entered 'None (0)'	System	24 Sep 2020 00:53:12
	System	24 Sep 2020 00:53:12

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:56', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '274422a0-34cc-47a0-a098-bae4df0905' User entered 'None (0)'	System	24 Sep 2020 00:53:12
	System	24 Sep 2020 00:53:12

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-23T19:52:58', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '274422a0-34cc-47a0-a098-bae4df0905' User entered 'None (0)'	System	24 Sep 2020 00:53:12
	System	24 Sep 2020 00:53:12

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-23T19:53:02', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '274422a0-34cc-47a0-a098-bae ad4df0905' User entered 'No (N)'	System	24 Sep 2020 00:53:12
	System	24 Sep 2020 00:53:12

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-23T19:53:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '274422a0-34cc-47a0-a098-bae ad4df0905' User entered '23 Sep 2020 19:53'	System	24 Sep 2020 00:53:12
	System	24 Sep 2020 00:53:12

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 4'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T18:00:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c3439765-8b5c-48db-b245-29eb6517acb4' User entered 'None (0)'	System	24 Sep 2020 23:01:30
	System	24 Sep 2020 23:01:30

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T18:00:55', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c3439765-8b5c-48db-b245-29eb6517acb4' User entered 'None (0)'	System	24 Sep 2020 23:01:30
	System	24 Sep 2020 23:01:30

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T18:00:58', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c3439765-8b5c-48db-b245-29eb6517acb4' User entered 'None (0)'	System	24 Sep 2020 23:01:30
	System	24 Sep 2020 23:01:30

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-24T18:01:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c3439765-8b5c-48db-b245-29eb6517acb4' User entered 'None (0)'	System	24 Sep 2020 23:01:30
	System	24 Sep 2020 23:01:30

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-24T18:01:03', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c3439765-8b5c-48db-b245-29eb6517acb4' User entered 'None (0)'	System	24 Sep 2020 23:01:30
	System	24 Sep 2020 23:01:30

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T18:01:05', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c3439765-8b5c-48db-b245-29eb6517acb4' User entered 'None (0)'	System	24 Sep 2020 23:01:30
	System	24 Sep 2020 23:01:30

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T18:01:08', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c3439765-8b5c-48db-b245-29eb6517acb4' User entered 'No (N)'	System	24 Sep 2020 23:01:30
	System	24 Sep 2020 23:01:30

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-24T18:01:28', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c3439765-8b5c-48db-b245-29eb6517acb4' User entered '24 Sep 2020 18:01'	System	24 Sep 2020 23:01:30
	System	24 Sep 2020 23:01:30

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 5'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:27:13', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4b90b9db-8118-4732-9b50-9f8ac9419ee9' User entered 'None (0)'	System	26 Sep 2020 01:27:42
	System	26 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-25T20:27:16', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4b90b9db-8118-4732-9b50-9f8ac9419ee9' User entered 'None (0)'	System	26 Sep 2020 01:27:42
	System	26 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:27:19', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4b90b9db-8118-4732-9b50-9f8ac9419ee9' User entered 'None (0)'	System	26 Sep 2020 01:27:42
	System	26 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AF AF)', Time: '2020-09-25T20:27:21', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4b90b9db-8118-4732-9b50-9f8ac9419ee9' User entered 'None (0)'	System	26 Sep 2020 01:27:42
	System	26 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-25T20:27:24', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4b90b9db-8118-4732-9b50-9f8ac9419ee9' User entered 'None (0)'	System	26 Sep 2020 01:27:42
	System	26 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-25T20:27:26', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4b90b9db-8118-4732-9b50-9f8ac9419ee9' User entered 'None (0)'	System	26 Sep 2020 01:27:42
	System	26 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-25T20:27:30', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4b90b9db-8118-4732-9b50-9f8ac9419ee9' User entered 'No (N)'	System	26 Sep 2020 01:27:42
	System	26 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-25T20:27:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '4b90b9db-8118-4732-9b50-9f8ac9419ee9' User entered '25 Sep 2020 20:27'	System	26 Sep 2020 01:27:42
	System	26 Sep 2020 01:27:42

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 6'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:02:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b91ad59f-1858-4869-847a-0f5dc789e9e9' User entered 'None (0)'	System	27 Sep 2020 01:02:53
	System	27 Sep 2020 01:02:53

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:02:12', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b91ad59f-1858-4869-847a-0f5dc789e9e9' User entered 'None (0)'	System	27 Sep 2020 01:02:53
	System	27 Sep 2020 01:02:53

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:02:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b91ad59f-1858-4869-847a-0f5dc789e9e9' User entered 'None (0)'	System	27 Sep 2020 01:02:53
	System	27 Sep 2020 01:02:53

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:02:18', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b91ad59f-1858-4869-847a-0f5dc789e9e9' User entered 'None (0)'	System	27 Sep 2020 01:02:53
	System	27 Sep 2020 01:02:53

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:02:24', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b91ad59f-1858-4869-847a-0f5dc789e9e9' User entered 'None (0)'	System	27 Sep 2020 01:02:53
	System	27 Sep 2020 01:02:53

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:02:26', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b91ad59f-1858-4869-847a-0f5dc789e9e9' User entered 'None (0)'	System	27 Sep 2020 01:02:53
	System	27 Sep 2020 01:02:53

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:02:36', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b91ad59f-1858-4869-847a-0f5dc789e9e9' User entered 'No (N)'	System	27 Sep 2020 01:02:53
	System	27 Sep 2020 01:02:53

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-26T20:02:48', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'b91ad59f-1858-4869-847a-0f5dc789e9e9' User entered '26 Sep 2020 20:02'	System	27 Sep 2020 01:02:53
	System	27 Sep 2020 01:02:53

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
Data entry locked.	System	21 Sep 2020 15:21:29
User entered 'Day 7'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '295d5842-f37a-4fc3-a3a0-3469fb4b7ead' User entered 'None (0)'	System	28 Sep 2020 01:28:36
	System	28 Sep 2020 01:28:36

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:12', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '295d5842-f37a-4fc3-a3a0-3469fb4b7ead' User entered 'None (0)'	System	28 Sep 2020 01:28:36
	System	28 Sep 2020 01:28:36

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '295d5842-f37a-4fc3-a3a0-3469fb4b7ead' User entered 'None (0)'	System	28 Sep 2020 01:28:36
	System	28 Sep 2020 01:28:36

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:18', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '295d5842-f37a-4fc3-a3a0-3469fb4b7ead' User entered 'None (0)'	System	28 Sep 2020 01:28:36
	System	28 Sep 2020 01:28:36

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:20', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '295d5842-f37a-4fc3-a3a0-3469fb4b7ead' User entered 'None (0)'	System	28 Sep 2020 01:28:36
	System	28 Sep 2020 01:28:36

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:22', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '295d5842-f37a-4fc3-a3a0-3469fb4b7ead' User entered 'None (0)'	System	28 Sep 2020 01:28:36
	System	28 Sep 2020 01:28:36

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

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)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:26', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '295d5842-f37a-4fc3-a3a0-3469fb4b7ead' User entered 'No (N)'	System	28 Sep 2020 01:28:36
	System	28 Sep 2020 01:28:36

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-09-27T20:28:35', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '295d5842-f37a-4fc3-a3a0-3469fb4b7ead' User entered '27 Sep 2020 20:28'	System	28 Sep 2020 01:28:36
	System	28 Sep 2020 01:28:36

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:21:29

US3852015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:05:43
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:21:29

US3852015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Jackie Ziegler (b) (4)	27 Oct 2020 18:51:32

US3852015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Jackie Ziegler (b) (4)	27 Oct 2020 18:51:32

US3852015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Oct 2020 18:51:32

US3852015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'pt was not assigned to a nurse'	Jackie Ziegler (b) (4)	27 Oct 2020 18:51:32

US3852015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	06 Oct 2020 16:19:01

US3852015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	06 Oct 2020 16:19:01

US3852015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	06 Oct 2020 16:27:09

US3852015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '6 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	06 Oct 2020 16:27:09
	(b) (4)	

US3852015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	06 Oct 2020 16:27:09

US3852015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	06 Oct 2020 16:27:09
	(b) (4)	

US3852015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	06 Oct 2020 16:27:28

US3852015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	06 Oct 2020 16:27:28

US3852015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	12 Oct 2020 20:43:41

US3852015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '12 Oct 2020'	Jackie Ziegler (b) (4)	12 Oct 2020 20:43:41

US3852015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4)	12 Oct 2020 20:43:41

US3852015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Jackie Ziegler (b) (4)	12 Oct 2020 20:43:41

US3852015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	12 Oct 2020 20:43:47

US3852015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	12 Oct 2020 20:43:47

US3852015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Lisa Huse (b) (4)	19 Oct 2020 17:56:30

US3852015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Oct 2020'	Lisa Huse (b) (4)	19 Oct 2020 17:56:30

US3852015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Clinic (Clinic)'	Lisa Huse (b) (4)	19 Oct 2020 17:56:30

US3852015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'VISIT3'	System	19 Oct 2020 17:56:30

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Oct 2020'	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '09:09'	(b) (4) Lisa Huse (b) (4) (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '19 Oct 2020 09:09'	System	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.3' F	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)'	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'infrared/forehead'	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '58'	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'bpm'	System	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '16'	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'breaths/min'	System	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '122'	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '67'	Lisa Huse (b) (4)	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'mmHg'	System	19 Oct 2020 17:58:19

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58

US3852015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58

US3852015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	Lisa Huse (b) (4)	19 Oct 2020 17:56:36

US3852015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Lisa Huse (b) (4)	19 Oct 2020 17:56:36

US3852015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Lisa Huse (b) (4)	19 Oct 2020 17:57:10

US3852015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Oct 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	19 Oct 2020 17:57:10

US3852015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '09:40'	(b) (4) Lisa Huse (b) (4) (b) (4)	19 Oct 2020 17:57:10

US3852015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered '19 Oct 2020 09:40'	System	19 Oct 2020 17:57:10

US3852015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Lisa Huse (b) (4)	19 Oct 2020 17:56:42

US3852015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	19 Oct 2020 17:56:42

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 64'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

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Generated On: 10 Jun 2021 10:03:24

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3852015

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
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US3852015

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[Date and time of submission](#)

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

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Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 71'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

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[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

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Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:24

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
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US3852015

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered 'Day 78'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
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US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 18:47:20

US3852015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:49:06
Data entry locked.	System	24 Aug 2020 18:47:20
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 18:47:20

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-11-28T15:57:38', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '93004b04-00be-4092-96d7-b6a535f71b87'	System	28 Nov 2020 21:58:01
User entered 'No (N)'	System	28 Nov 2020 21:58:01

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-11-28T15:57:45', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '93004b04-00be-4092-96d7-b6a535f71b87' User entered 'No (N)'	System	28 Nov 2020 21:58:01

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-11-28T15:57:58', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '93004b04-00be-4092-96d7-b6a535f71b87' User entered '28 Nov 2020 15:57:58'	System	28 Nov 2020 21:58:01
	System	28 Nov 2020 21:58:01

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-05T17:59:30', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '2f6f69fe-2088-4bf4-bd04-2e218c76522f' User entered 'No (N)'	System	05 Dec 2020 23:59:48
	System	05 Dec 2020 23:59:48

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-05T17:59:35', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '2f6f69fe-2088-4bf4-bd04-2e218c76522f' User entered 'No (N)'	System	05 Dec 2020 23:59:48

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-05T17:59:47', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '2f6f69fe-2088-4bf4-bd04-2e218c76522f' User entered '05 Dec 2020 17:59:47'	System	05 Dec 2020 23:59:48
	System	05 Dec 2020 23:59:48

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-11T13:15:43', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a87ed8ec-7000-4ef5-bdf7-79ed4e8e8aa8' User entered 'No (N)'	System	11 Dec 2020 19:16:11
	System	11 Dec 2020 19:16:11

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-11T13:15:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a87ed8ec-7000-4ef5-bdf7-79ed4e8e8aa8' User entered 'No (N)'	System	11 Dec 2020 19:16:11
	System	11 Dec 2020 19:16:11

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-11T13:16:08', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a87ed8ec-7000-4ef5-bdf7-79ed4e8e8aa8'	System	11 Dec 2020 19:16:11
User entered '11 Dec 2020 13:16:08'	System	11 Dec 2020 19:16:11

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:56:34', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered 'Yes (Y)'	System	24 Dec 2020 05:58:24
	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:55:34', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered 'No (N)'	System	24 Dec 2020 05:58:24
	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:56:53', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered 'Yes (Y)'	System	24 Dec 2020 05:58:24
	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '1'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '1'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '1'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '1'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '1'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '1'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '1'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '0'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:27', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed'	System	24 Dec 2020 05:58:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:57:57', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered 'No (N)'	System	24 Dec 2020 05:58:24
	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-23T23:58:15', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'a28d8858-6981-4f44-a100-7ffa669fe5ed' User entered '23 Dec 2020 23:58:15'	System	24 Dec 2020 05:58:24
	System	24 Dec 2020 05:58:24

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-30T00:07:12', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '9a8e0de6-db73-4cb8-babf-62b8b5ad437c' User entered 'No (N)'	System	30 Dec 2020 06:07:58
	System	30 Dec 2020 06:07:58

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-30T00:07:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '9a8e0de6-db73-4cb8-babf-62b8b5ad437c' User entered 'No (N)'	System	30 Dec 2020 06:07:58
	System	30 Dec 2020 06:07:58

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2020-12-30T00:07:56', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '9a8e0de6-db73-4cb8-babf-62b8b5ad437c' User entered '30 Dec 2020 00:07:56'	System	30 Dec 2020 06:07:58
	System	30 Dec 2020 06:07:58

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-09T08:53:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'adc7ce14-81b7-4693-9551-b96eeec91993'	System	09 Jan 2021 14:54:11
User entered 'No (N)'	System	09 Jan 2021 14:54:11

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-09T08:54:01', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'adc7ce14-81b7-4693-9551-b96eeec91993'	System	09 Jan 2021 14:54:11
User entered 'No (N)'	System	09 Jan 2021 14:54:11

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-09T08:54:10', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'adc7ce14-81b7-4693-9551-b96eeec91993' User entered '09 Jan 2021 08:54:10'	System	09 Jan 2021 14:54:11
	System	09 Jan 2021 14:54:11

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-14T16:54:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'd9e56f6a-9632-4fdf-82f6-816f41380fdc' User entered 'No (N)'	System	14 Jan 2021 22:55:00

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-14T16:54:48', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'd9e56f6a-9632-4fdf-82f6-816f41380fdc' User entered 'No (N)'	System	14 Jan 2021 22:55:00

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-14T16:54:55', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'd9e56f6a-9632-4fdf-82f6-816f41380fdc' User entered '14 Jan 2021 16:54:55'	System	14 Jan 2021 22:55:00

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-20T07:26:28', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3c2842b1-c8e4-41b9-b67d-f5126e758640' User entered 'No (N)'	System	20 Jan 2021 13:26:50
	System	20 Jan 2021 13:26:50

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-20T07:26:39', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3c2842b1-c8e4-41b9-b67d-f5126e758640'	System	20 Jan 2021 13:26:50
User entered 'No (N)'	System	20 Jan 2021 13:26:50

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-20T07:26:44', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3c2842b1-c8e4-41b9-b67d-f5126e758640' User entered '20 Jan 2021 07:26:44'	System	20 Jan 2021 13:26:50
	System	20 Jan 2021 13:26:50

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-27T09:32:43', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3d0702e0-18bb-47ca-ac1d-7dfe77d16ca1'	System	27 Jan 2021 15:32:57
User entered 'No (N)'	System	27 Jan 2021 15:32:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-27T09:32:48', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3d0702e0-18bb-47ca-ac1d-7dfe77d16ca1'	System	27 Jan 2021 15:32:57
User entered 'No (N)'	System	27 Jan 2021 15:32:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-01-27T09:32:55', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '3d0702e0-18bb-47ca-ac1d-7dfe77d16ca1' User entered '27 Jan 2021 09:32:55'	System	27 Jan 2021 15:32:57
	System	27 Jan 2021 15:32:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-03T21:00:56', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '01e11f3c-7393-4a3d-b54c-42e761b2e95f' User entered 'No (N)'	System	04 Feb 2021 03:01:34
	System	04 Feb 2021 03:01:34

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-03T21:01:06', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '01e11f3c-7393-4a3d-b54c-42e761b2e95f' User entered 'No (N)'	System	04 Feb 2021 03:01:34
	System	04 Feb 2021 03:01:34

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-03T21:01:11', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '01e11f3c-7393-4a3d-b54c-42e761b2e95f' User entered '03 Feb 2021 21:01:11'	System	04 Feb 2021 03:01:34
	System	04 Feb 2021 03:01:34

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-11T15:20:21', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f3054d22-3f48-4478-a24f-ea41e57bae4a' User entered 'No (N)'	System	11 Feb 2021 21:20:41
	System	11 Feb 2021 21:20:41

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-11T15:20:27', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f3054d22-3f48-4478-a24f-ea41e57bae4a'	System	11 Feb 2021 21:20:41
User entered 'No (N)'	System	11 Feb 2021 21:20:41

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-11T15:20:34', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'f3054d22-3f48-4478-a24f-ea41e57bae4a' User entered '11 Feb 2021 15:20:34'	System	11 Feb 2021 21:20:41
	System	11 Feb 2021 21:20:41

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-17T07:37:11', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '465ab69b-8082-4971-a24a-2afa2099ca76' User entered 'No (N)'	System	17 Feb 2021 13:37:26
	System	17 Feb 2021 13:37:26

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-17T07:37:19', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '465ab69b-8082-4971-a24a-2afa2099ca76' User entered 'No (N)'	System	17 Feb 2021 13:37:26
	System	17 Feb 2021 13:37:26

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-17T07:37:25', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '465ab69b-8082-4971-a24a-2afa2099ca76' User entered '17 Feb 2021 07:37:25'	System	17 Feb 2021 13:37:26
	System	17 Feb 2021 13:37:26

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-24T06:11:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '55817c8e-5b5e-4d82-bec0-44d6ba60141e' User entered 'No (N)'	System	24 Feb 2021 12:12:05
	System	24 Feb 2021 12:12:05

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-24T06:11:45', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '55817c8e-5b5e-4d82-bec0-44d6ba60141e' User entered 'No (N)'	System	24 Feb 2021 12:12:05
	System	24 Feb 2021 12:12:05

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-02-24T06:12:01', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '55817c8e-5b5e-4d82-bec0-44d6ba60141e' User entered '24 Feb 2021 06:12:01'	System	24 Feb 2021 12:12:05
	System	24 Feb 2021 12:12:05

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-03T07:00:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c9a318b4-f446-43fe-999c-24d75d1a9f36'	System	03 Mar 2021 13:01:00
User entered 'No (N)'	System	03 Mar 2021 13:01:00

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-03T07:00:50', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c9a318b4-f446-43fe-999c-24d75d1a9f36'	System	03 Mar 2021 13:01:00
User entered 'No (N)'	System	03 Mar 2021 13:01:00

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-03T07:00:57', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: 'c9a318b4-f446-43fe-999c-24d75d1a9f36'	System	03 Mar 2021 13:01:00
User entered '03 Mar 2021 07:00:57'	System	03 Mar 2021 13:01:00

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-12T11:40:40', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '413a3f93-47f7-475a-9dab-c3594123812a' User entered 'No (N)'	System	12 Mar 2021 17:40:51
	System	12 Mar 2021 17:40:51

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-12T11:40:45', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '413a3f93-47f7-475a-9dab-c3594123812a' User entered 'No (N)'	System	12 Mar 2021 17:40:51
	System	12 Mar 2021 17:40:51

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-12T11:40:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '413a3f93-47f7-475a-9dab-c3594123812a' User entered '12 Mar 2021 11:40:49'	System	12 Mar 2021 17:40:51
	System	12 Mar 2021 17:40:51

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-18T23:26:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1a2d8acf-4c2b-4150-9aea-7db6bebc29a9'	System	19 Mar 2021 04:26:14
User entered 'No (N)'	System	19 Mar 2021 04:26:14

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-18T23:26:04', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1a2d8acf-4c2b-4150-9aea-7db6bebc29a9'	System	19 Mar 2021 04:26:14
User entered 'No (N)'	System	19 Mar 2021 04:26:14

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-18T23:26:09', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1a2d8acf-4c2b-4150-9aea-7db6bebc29a9' User entered '18 Mar 2021 23:26:09'	System	19 Mar 2021 04:26:14
	System	19 Mar 2021 04:26:14

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-24T15:00:21', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '38e4366d-caf7-42af-8983-2070bbd57c8f' User entered 'No (N)'	System	24 Mar 2021 20:00:56
	System	24 Mar 2021 20:00:56

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-24T15:00:45', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '38e4366d-caf7-42af-8983-2070bbd57c8f' User entered 'No (N)'	System	24 Mar 2021 20:00:56

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-24T15:00:52', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '38e4366d-caf7-42af-8983-2070bbd57c8f' User entered '24 Mar 2021 15:00:52'	System	24 Mar 2021 20:00:56
	System	24 Mar 2021 20:00:56

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-04T18:18:17', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '20bf34e6-d057-4773-9922-36d669aff8d9' User entered 'Yes (Y)'	System	04 Apr 2021 23:19:57
	System	04 Apr 2021 23:19:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-04T18:18:25', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '20bf34e6-d057-4773-9922-36d669aff8d9' User entered 'No (N)'	System	04 Apr 2021 23:19:57
	System	04 Apr 2021 23:19:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-04T18:18:33', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '20bf34e6-d057-4773-9922-36d669aff8d9' User entered 'No (N)'	System	04 Apr 2021 23:19:57
	System	04 Apr 2021 23:19:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-04T18:18:49', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '20bf34e6-d057-4773-9922-36d669aff8d9' User entered 'Yes (Y)'	System	04 Apr 2021 23:19:57
	System	04 Apr 2021 23:19:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-04T18:19:13', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '20bf34e6-d057-4773-9922-36d669aff8d9'	System	04 Apr 2021 23:19:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Apr 2021 23:19:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-04T18:19:46', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '20bf34e6-d057-4773-9922-36d669aff8d9'	System	04 Apr 2021 23:19:57
User entered '04 Apr 2021 18:19:46'	System	04 Apr 2021 23:19:57

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-10T00:47:42', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '222807e6-7576-4434-b9db-c40010f10920'	System	10 Apr 2021 05:48:41
User entered 'No (N)'	System	10 Apr 2021 05:48:41

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-10T00:47:47', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '222807e6-7576-4434-b9db-c40010f10920'	System	10 Apr 2021 05:48:41
User entered 'No (N)'	System	10 Apr 2021 05:48:41

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-10T00:47:51', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '222807e6-7576-4434-b9db-c40010f10920'	System	10 Apr 2021 05:48:41
User entered '10 Apr 2021 00:47:51'	System	10 Apr 2021 05:48:41

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-16T09:49:22', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1f36b74d-dc1f-40b7-a4f3-7fe4b2c17429'	System	16 Apr 2021 14:49:35
User entered 'No (N)'	System	16 Apr 2021 14:49:35

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-16T09:49:28', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1f36b74d-dc1f-40b7-a4f3-7fe4b2c17429'	System	16 Apr 2021 14:49:35
User entered 'No (N)'	System	16 Apr 2021 14:49:35

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-16T09:49:31', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '1f36b74d-dc1f-40b7-a4f3-7fe4b2c17429' User entered '16 Apr 2021 09:49:31'	System	16 Apr 2021 14:49:35
	System	16 Apr 2021 14:49:35

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-23T08:28:34-05:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '9b510c0f-2292-455f-9cb5-49e803b9f9cc'	System	23 Apr 2021 13:28:49
User entered 'No (N)'	System	23 Apr 2021 13:28:49

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-23T08:28:42-05:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '9b510c0f-2292-455f-9cb5-49e803b9f9cc'	System	23 Apr 2021 13:28:49
User entered 'No (N)'	System	23 Apr 2021 13:28:49

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-23T08:28:47-05:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '9b510c0f-2292-455f-9cb5-49e803b9f9cc'	System	23 Apr 2021 13:28:49
User entered '23 Apr 2021 08:28:47'	System	23 Apr 2021 13:28:49

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-28T06:50:20-05:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '8fa8257a-81fb-45e8-90c6-7ea08d64832f' User entered 'No (N)'	System	28 Apr 2021 23:05:51
	System	28 Apr 2021 23:05:51

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

Have you been exposed to someone with 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 (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-28T06:50:31-05:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '8fa8257a-81fb-45e8-90c6-7ea08d64832f' User entered 'No (N)'	System	28 Apr 2021 23:05:51
	System	28 Apr 2021 23:05:51

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-04-28T06:50:34-05:00', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '8fa8257a-81fb-45e8-90c6-7ea08d64832f' User entered '28 Apr 2021 06:50:34'	System	28 Apr 2021 23:05:51
	System	28 Apr 2021 23:05:51

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:49:06

US3852015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:49:06
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:49:06

US3852015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:03:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-01T06:05:13', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '0d6bdee9-aefa-4e8f-8499-b975e74e25fd'	System	01 Mar 2021 12:05:36
User entered 'Yes (Y)'	System	01 Mar 2021 12:05:36

US3852015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:03:24

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-01T06:05:02', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '0d6bdee9-aefa-4e8f-8499-b975e74e25fd'	System	01 Mar 2021 12:05:36
User entered 'No (N)'	System	01 Mar 2021 12:05:36

US3852015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:03:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:42:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (882F553D-0F05-48A9-9182-7921D675AFAF)', Time: '2021-03-01T06:05:26', User OID: 'PatientReportedOutcome (US3852015)', ODM File OID: '0d6bdee9-aefa-4e8f-8499-b975e74e25fd' User entered '01 Mar 2021 06:05:26'	System	01 Mar 2021 12:05:36
	System	01 Mar 2021 12:05:36

US3852015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	13 Nov 2020 16:44:51

US3852015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '13 Nov 2020'	Jackie Ziegler (b) (4)	13 Nov 2020 16:44:51

US3852015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4)	13 Nov 2020 16:44:51

US3852015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	Jackie Ziegler (b) (4)	13 Nov 2020 16:44:51

US3852015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	13 Nov 2020 16:44:55

US3852015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:00:58
User entered 'I'	System	13 Nov 2020 16:44:55

US3852015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 16:25:09
	(b) (4)	

US3852015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 16:25:09

US3852015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 16:25:09

US3852015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'patient is currently getting convalescent calls'	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 16:25:09

US3852015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 16:25:17

US3852015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User entered 'I'	System	21 Dec 2020 16:25:17

US3852015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	20 Jan 2021 19:22:12

US3852015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '20 Jan 2021'	Jackie Ziegler (b) (4)	20 Jan 2021 19:22:12

US3852015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	20 Jan 2021 19:22:12

US3852015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	20 Jan 2021 19:22:12
	(b) (4)	

US3852015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	20 Jan 2021 19:22:18

US3852015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User entered 'I'	System	20 Jan 2021 19:22:18

US3852015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 01:32:36
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	03 Mar 2021 17:45:24

US3852015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 01:32:36
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '19 Feb 2021'	(b) (4) Leslie Edwards (b) (4) (b) (4)	03 Mar 2021 17:45:24

US3852015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 01:32:36
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	03 Mar 2021 17:45:24

US3852015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 01:32:36
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	03 Mar 2021 17:45:24

US3852015

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 01:32:29
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	03 Mar 2021 17:45:30

US3852015

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:01:27
User entered 'I'	System	03 Mar 2021 17:45:30

US3852015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:23

US3852015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:23

US3852015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[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 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:23

US3852015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User entered 'VISIT4'	System	15 Mar 2021 14:29:23

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User entered empty.	System	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User entered empty.	System	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User entered empty.	System	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User entered empty.	System	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User entered empty.	System	30 Mar 2021 17:59:06

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45

US3852015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45

US3852015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:32

US3852015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:32

US3852015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:53

US3852015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:53

US3852015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '09:11'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:53

US3852015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User entered '15 Mar 2021 09:11'	System	15 Mar 2021 14:29:53

US3852015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:29:58

US3852015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:48:45
User entered 'I'	System	15 Mar 2021 14:29:58

US3852015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:22:53
	(b) (4)	

US3852015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '16 Apr 2021'	Jackie Ziegler (b) (4)	16 Apr 2021 15:22:53
	(b) (4)	

US3852015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	16 Apr 2021 15:22:53

US3852015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:22:53
	(b) (4)	

US3852015

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:23:09
	(b) (4)	

US3852015

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 15:23:09

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:03:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:23:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:03:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '10:15' reason for change: Data Entry Error	(b) (4)	
User entered '09:15'	Lisa Huse (b) (4)	18 Dec 2020 18:03:23
	(b) (4)	
	Lisa Huse (b) (4)	18 Dec 2020 15:23:45
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:03:24

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:00
User entered '18 Dec 2020 10:15'	System	18 Dec 2020 18:03:23
User entered '18 Dec 2020 09:15'	System	18 Dec 2020 15:23:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:03:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:23:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:03:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:23:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 1 (Day 1)'	Lisa Huse (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '14 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1-4. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:04:46
Query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1-4. If not collected, please consider recording these as NOT DONE' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 14:27:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 14:27:32
User opened query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1-4. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 14:20:54
User entered empty.	Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	15 Jan 2021 14:27:32
User entered empty.	System	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Jan 2021 14:27:32
User entered empty.	Leslie Edwards (b) (4)	18 Dec 2020 15:24:32
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered 'None (None)'	Lisa Huse (b) (4)	18 Dec 2020 17:58:55
	(b) (4)	
	Lisa Huse (b) (4)	18 Dec 2020 15:24:32
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:24:32

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Form: Symptom Log (2)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 2 (Day 2)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '15 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Jan 2021 14:27:49
User entered empty.	Leslie Edwards (b) (4)	18 Dec 2020 15:25:09
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	15 Jan 2021 14:27:49
User entered empty.	System	18 Dec 2020 15:25:09

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Jan 2021 14:27:49
User entered empty.	Leslie Edwards (b) (4)	18 Dec 2020 15:25:09
	(b) (4)	

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered 'None (None)'	Lisa Huse (b) (4)	18 Dec 2020 17:58:55
	(b) (4)	
	Lisa Huse (b) (4)	18 Dec 2020 15:25:09
	(b) (4)	

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:09

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	(b) (4), (b) (6)	09 Feb 2021 10:23:42
User entered 'Day 3 (Day 3)'	Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '16 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Jan 2021 14:27:59
User entered empty.	Leslie Edwards (b) (4)	18 Dec 2020 15:25:47
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	15 Jan 2021 14:27:59
User entered empty.	System	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Jan 2021 14:27:59
User entered empty.	Leslie Edwards (b) (4)	18 Dec 2020 15:25:47
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered 'None (None)'	Lisa Huse (b) (4)	18 Dec 2020 17:58:55
	(b) (4)	
	Lisa Huse (b) (4)	18 Dec 2020 15:25:47
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:25:47

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 4 (Day 4)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '17 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Jan 2021 14:28:10
User entered empty.	Leslie Edwards (b) (4)	18 Dec 2020 15:26:26
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	15 Jan 2021 14:28:10
User entered empty.	System	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Jan 2021 14:28:10
User entered empty.	Leslie Edwards (b) (4)	18 Dec 2020 15:26:26
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered 'None (None)'	Lisa Huse (b) (4)	18 Dec 2020 17:58:55
	(b) (4)	
	Lisa Huse (b) (4)	18 Dec 2020 15:26:26
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:26:26

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 5 (Day 5)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Jan 2021 14:28:19
User entered empty.	Leslie Edwards (b) (4)	18 Dec 2020 15:27:21
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	15 Jan 2021 14:28:19
User entered empty.	System	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.7' F reason for change: Data Entry Error	(b) (4)	
User entered empty.	Lisa Huse (b) (4)	18 Dec 2020 17:59:08
	(b) (4)	
	Lisa Huse (b) (4)	18 Dec 2020 15:27:21
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered 'None (None)'	Lisa Huse (b) (4)	18 Dec 2020 17:58:55
	(b) (4)	
	Lisa Huse (b) (4)	18 Dec 2020 15:27:21
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 15:27:21

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 6 (Day 6)'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:46:37
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98.1' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:46:37

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 7 (Day 7)'	(b) (4) Jackie Ziegler (b) (4)	20 Dec 2020 16:37:53
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '20 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '96'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.9' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	20 Dec 2020 16:37:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 8 (Day 8)'	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 21:23:53
	(b) (4)	

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '21 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.7' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: New Information	Jackie Ziegler (b) (4)	22 Dec 2020 18:27:44
User entered 'None (None)'	Jackie Ziegler (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: New Information	Jackie Ziegler (b) (4)	22 Dec 2020 18:27:44
User entered 'None (None)'	Jackie Ziegler (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 21:23:53

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 9 (Day 9)'	(b) (4) Jackie Ziegler (b) (4)	22 Dec 2020 18:28:52
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '22 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.2' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: New Information	Jackie Ziegler (b) (4)	23 Dec 2020 18:23:36
User entered 'None (None)'	Jackie Ziegler (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	22 Dec 2020 18:28:52

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 10 (Day 10)'	(b) (4) Jackie Ziegler (b) (4)	23 Dec 2020 18:25:11
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '23 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98.2' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	23 Dec 2020 18:25:11

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 11 (Day 11)'	(b) (4) Jackie Ziegler (b) (4)	24 Dec 2020 15:50:17
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '24 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.6' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Dec 2020 15:50:17

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 12 (Day 12)'	(b) (4) Jackie Ziegler (b) (4)	25 Dec 2020 20:33:18
	(b) (4)	

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '25 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '99'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.6' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Dec 2020 20:33:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 13 (Day 13)'	(b) (4) Jackie Ziegler (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '26 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.1' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Dec 2020 16:42:30

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 14 (Day 14)'	(b) (4) Jackie Ziegler (b) (4)	28 Dec 2020 02:45:07
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '27 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '99'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.2' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4)	
	Jackie Ziegler (b) (4)	28 Dec 2020 20:39:34
User entered 'None (None)'	(b) (4)	
	Jackie Ziegler (b) (4)	28 Dec 2020 02:45:07
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: New Information	Jackie Ziegler (b) (4)	29 Dec 2020 19:49:39
User entered 'None (None)'	Jackie Ziegler (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 02:45:07

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 15 (Day 15)'	(b) (4) Jackie Ziegler (b) (4)	28 Dec 2020 20:39:18
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '28 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.9' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Moderate (Moderate)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: New Information	Jackie Ziegler (b) (4)	29 Dec 2020 19:49:26
User entered 'None (None)'	Jackie Ziegler (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	28 Dec 2020 20:39:18

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 16 (Day 16)'	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:49:12
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '29 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.2' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:49:12

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 17 (Day 17)'	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 17:59:15
	(b) (4)	

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Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '30 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.2' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)' reason for change: New Information	Jackie Ziegler (b) (4)	31 Dec 2020 18:01:46
User entered 'None (None)'	Jackie Ziegler (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	30 Dec 2020 17:59:15

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Day 18 (Day 18)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 18:02:45
	(b) (4)	

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '31 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 18:02:45

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	(b) (4), (b) (6)	09 Feb 2021 10:23:42
User entered 'Day 19 (Day 19)'	Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '1 Jan 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	(b) (4), (b) (6)	09 Feb 2021 10:23:42
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	01 Jan 2021 19:32:28

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User signature succeeded.	(b) (4), (b) (6)	09 Feb 2021 10:23:42
User entered 'Day 20 (Day 20)'	Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '2 Jan 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
User entered '%'	System	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.4' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:03:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:50:12
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	02 Jan 2021 20:41:56

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:03:24

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:03:24

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:03:24

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:07:06
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Positive' (Site from System).	Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:28:08
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	26 Jan 2021 21:26:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:26:29
User entered 'No (N)'	Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:03:24

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:03:24

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Lisa Huse (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:03:24

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:03:24

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:28
User entered '1'	System	26 Jan 2021 21:26:29
User entered '0'	System	18 Dec 2020 17:59:23

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

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Generated On: 10 Jun 2021 10:03:24

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

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Generated On: 10 Jun 2021 10:03:24

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

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US3852015

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[End Date](#)

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User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

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User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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[End Date](#)

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User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

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User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:03:24

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	26 Jan 2021 21:27:03

US3852015

Folder: Covid-19 Assessment 18 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:03:24

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:51:44
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'No (N)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	03 Mar 2021 18:49:37

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:03:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
User accepted default value 'Day 3 (Day 3)'	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:03:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Please correct and confirm in query response once updated. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 06:14:16
Query 'Per GCL Lab Reconciliation: Saliva: Please correct and confirm in query response once updated. Thank you.' answered with 'Corrected in PPD' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	05 Feb 2021 17:34:01
User opened query 'Per GCL Lab Reconciliation: Saliva: Please correct and confirm in query response once updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:53:25
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20DEC2020 is recorded under Illness visit 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)	19 Jan 2021 08:53:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20DEC2020 is recorded under Illness visit 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 'Confirmed sample is at lab-will correct collection date with lab' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	14 Jan 2021 16:14:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20DEC2020 is recorded under Illness visit 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)	29 Dec 2020 07:47:07

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '20 Dec 2020'	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:03:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
User accepted default value 'Day 5 (Day 5)'	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:03:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '22 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:03:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
User accepted default value 'Day 7 (Day 7)'	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:03:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Lisa Huse (b) (4)	28 Dec 2020 19:21:37
	(b) (4)	
	Lisa Huse (b) (4)	23 Dec 2020 21:40:15
	(b) (4)	

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24DEC2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:51:21
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24DEC2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' answered with 'Confirmed present and correct in PPD' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	10 Feb 2021 19:52:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24DEC2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:14:54
User entered '24 Dec 2020' reason for change: Data Entry Error	Lisa Huse (b) (4) (b) (4)	28 Dec 2020 19:21:37
User entered empty.	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:03:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
User accepted default value 'Day 9 (Day 9)'	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:03:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Lisa Huse (b) (4)	28 Dec 2020 19:21:37
	(b) (4)	
	Lisa Huse (b) (4)	23 Dec 2020 21:40:15
	(b) (4)	

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 26DEC2020 for Day 9 is recorded in EDC, however sample is reported with 28DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:51:27
Query 'Per GCL Lab Recon: Saliva: Sample dated 26DEC2020 for Day 9 is recorded in EDC, however sample is reported with 28DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'Confirmed present and correct in PPD' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	10 Feb 2021 19:52:53
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 26DEC2020 for Day 9 is recorded in EDC, however sample is reported with 28DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 08:23:00
User entered '26 Dec 2020' reason for change: Data Entry Error	Lisa Huse (b) (4) (b) (4)	28 Dec 2020 19:21:37
User entered empty.	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:03:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
User accepted default value 'Day 14 (Day 14)'	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:03:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lisa Huse (b) (4)	28 Jan 2021 16:16:37
User entered 'No (N)'	(b) (4)	
	Lisa Huse (b) (4)	23 Dec 2020 21:40:15
	(b) (4)	

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User closed query 'Per CDM: Was Saliva Collected?' is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 10:18:38
' (Site from DM).		
Query 'Per CDM: Was Saliva Collected?' is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.	Lisa Huse (b) (4)	28 Jan 2021 16:16:49
' answered with 'update' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Was Saliva Collected?' is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.	(b) (4), (b) (6)	22 Jan 2021 11:00:16
' (Site from DM).		
Query 'US3852015	(b) (4), (b) (6)	22 Jan 2021 11:00:04
' canceled (Site from DM).		
User opened query 'US3852015	(b) (4), (b) (6)	22 Jan 2021 11:00:01
' (Site from DM).		
User entered '31 Dec 2020' reason for change: Data Entry Error	Lisa Huse (b) (4)	13 Jan 2021 15:57:32
User entered empty.	(b) (4)	
	Lisa Huse (b) (4)	23 Dec 2020 21:40:15
	(b) (4)	

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:03:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
User accepted default value 'Day 21 (Day 21)'	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:03:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Lisa Huse (b) (4)	13 Jan 2021 15:57:32
	(b) (4)	
	Lisa Huse (b) (4)	23 Dec 2020 21:40:15
	(b) (4)	

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 07JAN2021 for Day 21 is recorded in EDC, however sample is reported with 11JAN2021 for Day 21 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:51:44
Query 'Per GCL Lab Recon: Saliva: Sample dated 07JAN2021 for Day 21 is recorded in EDC, however sample is reported with 11JAN2021 for Day 21 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'Date confirmed corrected in PPD to 7JAN2021' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	10 Feb 2021 19:53:39
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 07JAN2021 for Day 21 is recorded in EDC, however sample is reported with 11JAN2021 for Day 21 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 08:24:03
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 08:23:20
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Corrected in PPD' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	05 Feb 2021 17:34:22

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking 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)	29 Jan 2021 07:13:19
User entered '7 Jan 2021' reason for change: Data Entry Error	Lisa Huse (b) (4)	13 Jan 2021 15:57:32
User entered empty.	Lisa Huse (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:03:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
User accepted default value 'Day 28 (Day 28)'	Lisa Huse (b) (4) (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:03:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lisa Huse (b) (4)	14 Jan 2021 16:47:03
User entered 'No (N)'	(b) (4)	
	Lisa Huse (b) (4)	23 Dec 2020 21:40:15
	(b) (4)	

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:51:56
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number, tracking number and shipping date in query response for tracking purpose.' answered with 'Saliva sample results confirmed in PPD, so all samples have been received. No tracking data available.' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	22 Feb 2021 18:12:46
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:15:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking 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 Feb 2021 11:15:17
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Corrected in PPD' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	05 Feb 2021 17:34:54

US3852015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking 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)	29 Jan 2021 07:13:40
User entered '14 Jan 2021' reason for change: Data Entry Error	Lisa Huse (b) (4)	14 Jan 2021 16:47:03
User entered empty.	Lisa Huse (b) (4)	23 Dec 2020 21:40:15

US3852015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:39

US3852015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 08:55:02
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'Data corrected at lab' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	14 Jan 2021 16:16:49
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 08:09:31
User entered '18 Dec 2020'	Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:39

US3852015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Clinic (Clinic)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 17:59:39

US3852015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:07
User entered 'SICKD1'	System	18 Dec 2020 17:59:39

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '10:36'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
User entered '18 Dec 2020 10:36'	System	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '62' in	(b) (4) Lisa Huse (b) (4)	18 Dec 2020 18:00:20
DataPoint set to visible.	(b) (4) System	18 Dec 2020 17:59:39

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '136' lb	(b) (4) Lisa Huse (b) (4)	18 Dec 2020 18:00:20
DataPoint set to visible.	(b) (4) System	18 Dec 2020 17:59:39

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.7' F	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'infrared/forehead'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '67'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
User entered 'bpm'	System	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
User entered 'breaths/min'	System	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '126'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
User entered 'mmHg'	System	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '83'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15
User entered 'mmHg'	System	18 Dec 2020 18:00:20

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15

US3852015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:15

US3852015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:34

US3852015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:34

US3852015

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:03:24

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:24
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:40

US3852015

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:24
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18 Dec 2020'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:00:40

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:47:12

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '14 Jan 2021'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:47:12

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Clinic (Clinic)'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:47:12

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:33
User entered 'SICKD28'	System	14 Jan 2021 16:47:12

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '14 Jan 2021'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '08:30'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
User entered '14 Jan 2021 08:30'	System	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '62' in	(b) (4) Lisa Huse (b) (4)	14 Jan 2021 16:48:20
DataPoint set to visible.	(b) (4) System	14 Jan 2021 16:47:12

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '142' lb	(b) (4) Lisa Huse (b) (4)	14 Jan 2021 16:48:20
DataPoint set to visible.	(b) (4) System	14 Jan 2021 16:47:12

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '96.9' F	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'infrared/forehead'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '74'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
User entered 'bpm'	System	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '18'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
User entered 'breaths/min'	System	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '123'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
User entered 'mmHg'	System	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '81'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40
User entered 'mmHg'	System	14 Jan 2021 16:48:20

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:40

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:46
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:47:23

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:46
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '14 Jan 2021'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:47:23

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:03:24

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:53
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:47:28

US3852015

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:03:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:53
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:45:18
Query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you. ' answered with 'Sample is in PPD GCL-Ascension 1F60B0E' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	29 Jan 2021 19:42:30
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:40:43
User entered '14 Jan 2021'	Lisa Huse (b) (4) (b) (4)	14 Jan 2021 16:47:28

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:28:31

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:28:31

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:28:31

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 18:28:31

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:30:26

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:30:26

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 03:09:13
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 03:09:13
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered '1'	System	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'I'	System	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered empty.	System	21 Jan 2021 01:22:47
DataPoint set to visible.	System	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered empty.	System	21 Jan 2021 01:22:47
DataPoint set to visible.	System	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '11:56'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered '19 Jan 2021 11:56'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Infrared/forehead'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '64'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'bpm'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'breaths/min'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '132'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'mmHg'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '79'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'mmHg'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered empty.	System	21 Jan 2021 01:22:47
DataPoint set to visible.	System	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '12:45'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered '19 Jan 2021 12:45'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Infrared/forehead'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '64'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'bpm'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'breaths/min'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '132'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'mmHg'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '83'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'mmHg'	System	21 Jan 2021 01:22:47

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:20:42

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:20:42

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'mRNA-1273'	System	19 Jan 2021 18:30:18
DataPoint set to visible.	System	19 Jan 2021 18:29:06

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User closed query 'Per CDM : Subject had Open Label Day1 Treatment on 28JAN2021. Please review and reconcile. Thank You ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:36:14
Query 'Per CDM : Subject had Open Label Day1 Treatment on 28JAN2021. Please review and reconcile. Thank You ' answered with 'Per source 19JAN2021 is correct.' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	23 Apr 2021 13:17:28
User closed query 'Per CDM : Subject had Open Label Day1 Treatment on 28JAN2021. Please review and reconcile. Thank You ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 10:26:32
User opened query 'Per CDM : Subject had Open Label Day1 Treatment on 28JAN2021. Please review and reconcile. Thank You ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 10:26:30
Query 'Per CDM : Subject had Open Label Day1 Treatment on 28JAN2021. Please review and reconcile. Thank You ' answered with 'The date entered on this form is correct. The OL-1 dosing was entered into IRT late. A date change form was submitted' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:03:57
User opened query 'Per CDM : Subject had Open Label Day1 Treatment on 28JAN2021. Please review and reconcile. Thank You ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:56:27
User signature succeeded.	Leland Allen (b) (4) (b) (4)	09 Feb 2021 10:23:42
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '12:10'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered '19 Jan 2021 12:10'	System	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'ONCE'	System	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 18:30:18

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:20:19

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:20:19

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '12:00'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:20:19

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered '19 Jan 2021 12:00'	System	21 Jan 2021 01:20:19

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:19:50

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:03:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:19:50

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '11:45' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:20:05
User entered '12:00'	(b) (4), (b) (6)	21 Jan 2021 01:19:50

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:03:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered '19 Jan 2021 11:45'	System	21 Jan 2021 01:20:05
User entered '19 Jan 2021 12:00'	System	21 Jan 2021 01:19:50

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:18:00

US3852015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:06
User entered 'I'	System	21 Jan 2021 01:18:00

US3852015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:39:34
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:30:08

US3852015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:39:34
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:30:08

US3852015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:39:34
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:30:08

US3852015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:39:34
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:30:08

US3852015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:39:34
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:30:20

US3852015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:39:34
User entered 'I'	System	17 Feb 2021 15:30:20

US3852015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:39:34
User entered '1'	System	17 Feb 2021 15:30:20
DataPoint set to visible.	System	17 Feb 2021 15:30:20

US3852015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:30:50

US3852015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:30:50

US3852015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[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 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:30:50

US3852015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'OLD29'	System	17 Feb 2021 15:30:50

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '08:43'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered '17 Feb 2021 08:43'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Infrared/Forehead'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '64'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'bpm'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'breaths/min'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '119'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'mmHg'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '74'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'mmHg'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '09:20'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered '17 Feb 2021 09:20'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	17 Feb 2021 16:00:40
User entered '97.8' F reason for change: Data Entry Error	System	17 Feb 2021 16:00:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Leslie Edwards (b) (4)	17 Feb 2021 16:00:40
User entered '97.8' (non-conformant).	(b) (4)	17 Feb 2021 15:52:31
	(b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Infrared/Forehead'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '61'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'bpm'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'breaths/min'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '130'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'mmHg'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '81'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'mmHg'	System	17 Feb 2021 15:52:31

US3852015

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:46

US3852015

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:52:46

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

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)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'mRNA-1273'	System	17 Feb 2021 15:31:19
DataPoint set to visible.	System	17 Feb 2021 15:30:20

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '08:46'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered '17 Feb 2021 08:46'	System	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'ONCE'	System	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:24

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 15:31:19

US3852015

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:31:26

US3852015

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:04:10
User entered 'I'	System	17 Feb 2021 15:31:26

US3852015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:41
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	24 Feb 2021 17:07:46

US3852015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:41
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered '24 Feb 2021'	(b) (4) Jackie Ziegler (b) (4)	24 Feb 2021 17:07:46

US3852015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:41
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	24 Feb 2021 17:07:46

US3852015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:41
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	24 Feb 2021 17:07:46

US3852015

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:41
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	24 Feb 2021 17:07:51

US3852015

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:41
User entered 'I'	System	24 Feb 2021 17:07:51

US3852015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:33:20

US3852015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:33:20

US3852015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:33:20

US3852015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User entered 'OLD57'	System	15 Mar 2021 14:33:20

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '08:55'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User entered '15 Mar 2021 08:55'	System	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Infrared'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '60'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User entered 'bpm'	System	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '19'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User entered 'breaths/min'	System	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '129'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User entered 'mmHg'	System	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '81'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User entered 'mmHg'	System	15 Mar 2021 14:34:34

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06

US3852015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06

US3852015

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:41

US3852015

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:34:41

US3852015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:35:00

US3852015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:35:00

US3852015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
User entered '09:11'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:35:00

US3852015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:06
User entered '15 Mar 2021 09:11'	System	15 Mar 2021 14:35:00

US3852015

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:03:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:58:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)' reason for change: New Information	Jackie Ziegler (b) (4)	19 Dec 2020 15:47:08
User entered 'No (N)'	Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:56:22

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered	(b) (4)	23 Dec 2020 16:05:35
'USA-US076-2020-mRNA-1273-P301000011'	System	23 Dec 2020 16:05:35
User entered 'New'	(b) (4), (b) (6)	23 Dec 2020 16:05:35

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 17:09:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 17:09:02
Data point term sent to Coder	System	22 Dec 2020 17:07:58
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	Lisa Huse (b) (4)	22 Dec 2020 17:07:38
Coding entries removed.	(b) (4)	
	Lisa Huse (b) (4)	22 Dec 2020 17:07:23
	(b) (4)	
User entered 'Symptomatic VOCID-19' reason for change: Data Entry Error	Lisa Huse (b) (4)	22 Dec 2020 17:07:23
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	19 Dec 2020 15:48:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Dec 2020 15:48:39
	(b) (4)	
Data point term sent to Coder	System	19 Dec 2020 15:48:07
User entered 'cough'	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User closed query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:07:56
Query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' answered with 'Corrected' (Site from DM).	Leslie Edwards (b) (4)	22 Mar 2021 13:31:32
Signature has been broken.	(b) (4)	
	Leslie Edwards (b) (4)	22 Mar 2021 13:31:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	22 Mar 2021 13:31:16
User opened query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:02:56
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4)	
	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 17:07:23
User entered 'Yes (Y)'	Lisa Huse (b) (4)	19 Dec 2020 15:48:06
	Jackie Ziegler (b) (4)	
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 17:07:23
User entered 'No (N)'	Lisa Huse (b) (4)	19 Dec 2020 15:48:06
	Jackie Ziegler (b) (4)	
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '14 Dec 2020'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: New Information	(b) (4) Leslie Edwards (b) (4)	14 Jan 2021 16:09:40
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
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) (4), (b) (6)	15 Jan 2021 13:19:57
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 'Updated' (Site from Safety).	Leslie Edwards (b) (4) (b) (4)	14 Jan 2021 16:09:51
User entered '2 Jan 2021' reason for change: New Information	Leslie Edwards (b) (4) (b) (4)	14 Jan 2021 16:09:40
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)	30 Dec 2020 14:26:35
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Dec 2020 17:07:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 17:07:23
User entered 'No (N)' reason for change: Data Entry Error	Lisa Huse (b) (4)	22 Dec 2020 17:07:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Dec 2020 15:48:06
User entered empty.	System	19 Dec 2020 15:48:06
	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Dec 2020 17:07:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 17:07:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lisa Huse (b) (4)	22 Dec 2020 17:07:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Dec 2020 15:48:06
User entered empty.	System	19 Dec 2020 15:48:06
	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Dec 2020 17:07:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 17:07:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lisa Huse (b) (4)	22 Dec 2020 17:07:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Dec 2020 15:48:06
User entered empty.	System	19 Dec 2020 15:48:06
	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Dec 2020 17:07:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 17:07:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lisa Huse (b) (4)	22 Dec 2020 17:07:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Dec 2020 15:48:06
User entered empty.	System	19 Dec 2020 15:48:06
	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
Signature has been broken.	Leslie Edwards (b) (4)	24 Feb 2021 14:30:49
User entered '0' reason for change: Data Entry Error	Leslie Edwards (b) (4)	24 Feb 2021 14:30:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '1'	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
Signature has been broken.	Leslie Edwards (b) (4)	24 Feb 2021 14:30:49
User entered '1' reason for change: Data Entry Error	Leslie Edwards (b) (4)	24 Feb 2021 14:30:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:55
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Updated' (Site from Safety).	Leslie Edwards (b) (4) (b) (4)	14 Jan 2021 16:09:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Leslie Edwards (b) (4) (b) (4)	14 Jan 2021 16:09:40
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:26:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:48:06
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 17:07:23

US3852015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 13:31:16
User entered '0'	System	19 Dec 2020 15:48:06

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Jan 2021 19:41:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:41:09
Data point term sent to Coder	System	19 Jan 2021 18:27:27
User entered 'Sciatica left leg from chronic back pain'	Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '27 Dec 2020'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
User entered empty.	System	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '8 Jan 2021'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
User entered empty.	System	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Leslie Edwards (b) (4)	19 Jan 2021 18:26:32
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'l'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
User entered '0'	System	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07
User entered '1'	System	19 Jan 2021 18:26:32

US3852015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:03:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:13:07

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
User entered 'USA-US076-2021-mRNA-1273-P301000003'	(b) (4) System	19 Apr 2021 16:52:18
User entered 'New'	(b) (4), (b) (6)	19 Apr 2021 16:52:18

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:13:46
User closed query 'PV Query: Was the SAE considered a worsening of the subject's medical history of back pain? If so, please consider updating the event the event term accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 20:09:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 14:39:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 14:39:06
Data point term sent to Coder	System	30 Apr 2021 14:38:18
Query 'PV Query: Was the SAE considered a worsening of the subject's medical history of back pain? If so, please consider updating the event the event term accordingly.' answered with 'update' (Site from Safety).	Lisa Huse (b) (4) (b) (4)	30 Apr 2021 14:37:40
Coding entries removed.	Lisa Huse (b) (4) (b) (4)	30 Apr 2021 14:37:35
Signature has been broken.	Lisa Huse (b) (4) (b) (4)	30 Apr 2021 14:37:35
User entered 'Worsening BACK PAIN' reason for change: Data Entry Error	Lisa Huse (b) (4) (b) (4)	30 Apr 2021 14:37:35
User opened query 'PV Query: Was the SAE considered a worsening of the subject's medical history of back pain? If so, please consider updating the event the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:50:13
User signature succeeded.	Leland Allen (b) (4) (b) (4)	16 Apr 2021 20:31:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:29:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:29:48

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	16 Apr 2021 15:29:11
User entered 'back pain'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '28 Mar 2021'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Was the SAE considered a worsening of the subject's medical history of back pain? If so, please consider updating the event the event term accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:50:18
User opened query 'PV Query: Was the SAE considered a worsening of the subject's medical history of back pain? If so, please consider updating the event the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:04:34
User entered empty.	System	16 Apr 2021 15:28:37

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'No (N)'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '31 Mar 2021'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:28:37

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	16 Apr 2021 15:28:37

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '0'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	16 Apr 2021 15:28:37

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '28 Mar 2021'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '31 Mar 2021'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'No (N)'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '0'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'I'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 16:25:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 16:25:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lisa Huse (b) (4)	16 Apr 2021 16:25:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 15:28:37
User entered empty.	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 16:25:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 16:25:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lisa Huse (b) (4)	16 Apr 2021 16:25:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 15:28:37
User entered empty.	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 16:25:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 16:25:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lisa Huse (b) (4)	16 Apr 2021 16:25:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 15:28:37
User entered empty.	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

None

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '0'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'I'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'I'	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	16 Apr 2021 15:28:37

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37
	(b) (4)	

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[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)	30 Apr 2021 20:09:18
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 PCR test once on Monday 29March2021-negative result. ' (Site from Safety).	Lisa Huse (b) (4) (b) (4)	30 Apr 2021 14:34:38
User closed query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:57:51
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Con Med is listed' (Site from Safety).	Lisa Huse (b) (4) (b) (4)	28 Apr 2021 18:13:25
User closed 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)	28 Apr 2021 17:50:33
User closed query 'PV query: Please provide events leading up to the hospitalization' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 17:50:29
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.' answered with 'No results are available' (Site from Safety).	Lisa Huse (b) (4) (b) (4)	28 Apr 2021 13:34:57

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide events leading up to the hospitalization' answered with 'History of chronic back pain' (Site from Safety).	Lisa Huse (b) (4)	28 Apr 2021 13:34:40
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:03:47
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)	26 Apr 2021 20:03:11
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)	26 Apr 2021 20:02:16
User opened query 'PV query: Please provide events leading up to the hospitalization' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:01:39
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'admitted to hospital for back pain on 3/28/31, laminectomy/discectomy of L5 on 3/31/21, discharged 3/31/21'	(b) (4), Jackie Ziegler (b) (4)	16 Apr 2021 15:28:37

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 15:28:37

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 15:28:37

US3852015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:03:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 15:28:37

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:03:24

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:58:20
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:31:54
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'Added to Med history' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	25 Mar 2021 13:33:48
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:40:25
User signature succeeded.	Leland Allen (b) (4) (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)' reason for change: New Information	Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:57:56
User entered 'No (N)'	Caitlin roll (b) (4) (b) (4)	24 Aug 2020 20:36:02

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 15:20:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 15:20:52
Data point term sent to Coder	System	01 Sep 2020 15:00:07
User entered 'Clindamycin'	Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Prophylaxis tooth extraction (subject has prior joint replacement)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '300'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'mg (mg)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'three times daily (TID)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '31 Aug 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: New Information	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:44:29
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '6 Sep 2020' reason for change: New Information	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:44:29
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User entered '3'	System	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User entered '1'	System	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:22:25
User entered '804 (804)'	System	01 Sep 2020 14:59:15

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Sep 2020 01:16:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 01:16:45
Data point term sent to Coder	System	01 Sep 2020 15:01:08
User entered 'Ibuprofen'	Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Prophylaxis tooth extraction for swelling'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '800'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'mg (mg)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'three times daily (TID)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '31 Aug 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 18:16:57
User entered 'Yes (Y)'	Leslie Edwards (b) (4)	01 Sep 2020 15:00:25
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '6 Sep 2020' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 18:16:57
User entered empty.	Leslie Edwards (b) (4)	19 Jan 2021 18:16:57
	(b) (4)	
	Martha Bunnell-Pollak	01 Sep 2020 15:00:25
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User entered '3'	System	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User entered '1'	System	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:31:58
User entered '804 (804)'	System	01 Sep 2020 15:00:25

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:46:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:46:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:31:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:31:01
Data point term sent to Coder Coding entries removed.	System	04 Feb 2021 18:30:35
Coding entries removed.	Leslie Edwards (b) (4)	04 Feb 2021 18:29:53
User entered 'INFLUENZA VACCINE' reason for change: Data Entry Error	Leslie Edwards (b) (4)	04 Feb 2021 18:29:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 20:47:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 20:47:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 20:47:23

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	12 Oct 2020 20:47:23
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	12 Oct 2020 20:46:08
User entered 'seasonal influenza vaccine'	Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Prophylaxis for influenza' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	04 Feb 2021 18:29:53
User entered 'flu prevention'	(b) (4)	
	Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0.5' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	04 Feb 2021 18:29:53
User entered '1'	(b) (4)	
	Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	04 Feb 2021 18:29:53
User entered 'Other (OTHER)'	(b) (4)	
	Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty; reason for change Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	04 Feb 2021 18:29:53
User entered 'dose'	(b) (4)	
	Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'once (ONCE)'	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	12 Oct 2020 20:45:12

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '6 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '6 Oct 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	12 Oct 2020 20:45:12

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	12 Oct 2020 20:45:12
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User entered empty.	System	12 Oct 2020 20:45:12

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User entered empty.	System	12 Oct 2020 20:45:12

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:48:51
User entered empty.	System	12 Oct 2020 20:45:12

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Oct 2020 09:05:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 09:05:25
Data point term sent to Coder	System	16 Oct 2020 09:04:11
User entered 'Ambien'	(b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Insomnia'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered '5' reason for change: New Information	Leslie Edwards (b) (4)	19 Jan 2021 18:10:12
	(b) (4)	
User closed query 'Per CDM: Please review "Dose per administration" and update with either a number or "UNK" if unknown. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 10:35:14
Query 'Per CDM: Please review "Dose per administration" and update with either a number or "UNK" if unknown. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:35:20
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:34:56
	(b) (4), (b) (6)	
User opened query 'Per CDM: Please review "Dose per administration" and update with either a number or "UNK" if unknown. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:07:12
User entered 'N'	(b) (4), (b) (6)	16 Oct 2020 09:03:49
	(b) (4), (b) (6)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered 'mg (mg)' reason for change: New Information	Leslie Edwards (b) (4)	19 Jan 2021 18:10:12
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 15:35:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 15:35:11
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:35:11
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 15:34:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:34:56
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered empty; reason for change Data Entry Error	Leslie Edwards (b) (4)	19 Jan 2021 18:10:12
	(b) (4)	
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:35:11
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. (Site from DM). Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 12:20:08
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. (Site from DM).	Leslie Edwards (b) (4) (b) (4)	13 Nov 2020 16:11:29
User entered 'UN UNK 2010'	(b) (4), (b) (6)	13 Nov 2020 10:55:13
	(b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 09:03:49

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:59:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:59:25
Data point term sent to Coder	System	13 Nov 2020 16:11:56
Coding entries removed.	Leslie Edwards (b) (4)	13 Nov 2020 16:11:48
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 09:06:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 09:06:20
Data point term sent to Coder	System	16 Oct 2020 09:05:11
User entered 'Estradiol'	(b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 12:20:24
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	13 Nov 2020 16:12:00
User entered 'Low estrogen level' reason for change: Data Entry Error	Leslie Edwards (b) (4) (b) (4)	13 Nov 2020 16:11:48
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:55:28
User entered 'Hormone Replacement'	(b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0.5'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'UN UNK 1997'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 09:04:59

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Oct 2020 09:07:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 09:07:32
Data point term sent to Coder	System	16 Oct 2020 09:06:12
User entered 'Levothyroxine'	(b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Hypothyroidism'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '50'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered 'ug (ug)'	(b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 09:05:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Oct 2020 09:08:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 09:08:28
Data point term sent to Coder	System	16 Oct 2020 09:07:12
User entered 'Pravastatin'	(b) (4), (b) (6) (b) (4)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '10'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 09:06:53

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 18:07:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 18:07:07
Data point term sent to Coder	System	19 Jan 2021 18:06:01
Coding entries removed.	Leslie Edwards (b) (4)	19 Jan 2021 18:05:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 15:55:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 15:55:37
Data point term sent to Coder	System	19 Dec 2020 15:55:09
Coding entries removed.	Jackie Ziegler (b) (4)	19 Dec 2020 15:54:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 15:53:36

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Dec 2020 15:53:36
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	19 Dec 2020 15:53:09
User entered 'mucinex'	Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User closed query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 15:45:58
Query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Corrected' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	24 Feb 2021 14:31:04
User opened query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:45:40
User signature succeeded.	Leland Allen (b) (4) (b) (4)	09 Feb 2021 10:23:33
User entered 'NASAL CONGESTION due to COVID-19' reason for change: Data Entry Error	Leslie Edwards (b) (4) (b) (4)	19 Jan 2021 18:05:40
User entered 'nasal congestion' reason for change: Data Entry Error	Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:54:16
User entered 'runny nose'	Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:52:57

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 10:34:46
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	02 Feb 2021 16:38:42
User entered '600' reason for change: Data Entry Error	Leslie Edwards (b) (4) (b) (4)	02 Feb 2021 16:38:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:25:10
User entered '0.5'	Jackie Ziegler (b) (4) (b) (4)	19 Dec 2020 15:52:57

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	02 Feb 2021 16:38:35
User entered 'tablet (TABLET)'	(b) (4)	
	Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Dec 2020 15:55:16
User entered 'twice daily (BID)' reason for change: Data Entry Error	System	19 Dec 2020 15:55:16
User opened query 'Data is required. Please complete.' (Site from System).	Jackie Ziegler (b) (4)	19 Dec 2020 15:55:16
User entered empty.	(b) (4)	
	System	19 Dec 2020 15:52:57
	Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '14 Dec 2020'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	19 Jan 2021 18:05:25
User entered 'Yes (Y)'	(b) (4)	
	Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 18:05:25
User entered empty.	Leslie Edwards (b) (4)	19 Jan 2021 18:05:25
	(b) (4)	
	Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 18:05:25
User entered 'Yes (Y)'	Leslie Edwards (b) (4)	19 Jan 2021 18:05:25
	(b) (4)	
	Jackie Ziegler (b) (4)	19 Dec 2020 15:52:57
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User entered '2'	System	19 Dec 2020 15:55:16
User entered empty.	System	19 Dec 2020 15:52:57

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User entered '1'	System	19 Dec 2020 15:55:16
User entered empty.	System	19 Dec 2020 15:52:57

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:44
User entered '804 (804)'	System	19 Dec 2020 15:55:16
User entered empty.	System	19 Dec 2020 15:52:57

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 18:11:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 18:11:07
Data point term sent to Coder Coding entries removed.	System Leslie Edwards (b) (4)	19 Jan 2021 18:10:05 19 Jan 2021 18:09:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 19:49:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 19:49:20
Data point term sent to Coder User entered 'robaxin'	System Jackie Ziegler (b) (4)	29 Dec 2020 19:48:25 29 Dec 2020 19:47:50

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'SCIATICA LEFT LEG' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	19 Jan 2021 18:09:35
User entered 'muscle aches'	(b) (4)	
	Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '750'	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'as needed (PRN)'	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '28 Dec 2020'	(b) (4) Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Dec 2020 19:47:50

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	19 Jan 2021 18:09:35
User entered 'Yes (Y)'	(b) (4)	
	Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '8 Jan 2021' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 18:09:35
User entered empty.	Leslie Edwards (b) (4)	19 Jan 2021 18:09:35
	(b) (4)	
	Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:28:02
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 10:20:37
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'Corrected' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	24 Feb 2021 14:31:19
Signature has been broken.	Leslie Edwards (b) (4) (b) (4)	24 Feb 2021 14:31:13
User entered 'No (N)' reason for change: Data Entry Error	Leslie Edwards (b) (4) (b) (4)	24 Feb 2021 14:31:13
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:46:30

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
	(b) (4)	
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	29 Dec 2020 19:47:50
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User entered empty.	System	29 Dec 2020 19:47:50

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User entered empty.	System	29 Dec 2020 19:47:50

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:12:07
User entered empty.	System	29 Dec 2020 19:47:50

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 23:52:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 23:52:12
Data point term sent to Coder	System	19 Jan 2021 18:10:06
Coding entries removed.	Leslie Edwards (b) (4)	19 Jan 2021 18:09:15
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)	30 Dec 2020 18:06:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 18:06:19
Data point term sent to Coder	System	30 Dec 2020 18:02:14
User entered 'ibuprofen'	Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'SCIATICA LEFT LEG' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	19 Jan 2021 18:09:15
User entered 'myalgia- bilateral legs'	(b) (4)	
	Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '400'	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'as needed (PRN)'	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '29 Dec 2020'	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	19 Jan 2021 18:08:55
User entered 'Yes (Y)'	(b) (4)	
	Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '8 Jan 2021' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 18:08:55
User entered empty.	Leslie Edwards (b) (4)	19 Jan 2021 18:08:55
	(b) (4)	
	Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	19 Jan 2021 18:08:55
User entered 'Yes (Y)'	(b) (4)	
	Jackie Ziegler (b) (4)	30 Dec 2020 18:01:58
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User entered empty.	System	30 Dec 2020 18:01:58

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User entered empty.	System	30 Dec 2020 18:01:58

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:33:05
User entered empty.	System	30 Dec 2020 18:01:58

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:20:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:20:44
Data point term sent to Coder	System	16 Apr 2021 15:31:13
User entered 'oxycodone'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'No (N)'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'surgical pain'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered '5/325'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'mg (mg)'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'as needed (PRN)'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'Oral (ORAL)'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '31 Mar 2021'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered 'No (N)'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '8 Apr 2021'	Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:31:03
	(b) (4)	

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:31:03

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:31:03

US3852015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:31:03

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:03:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:58:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:56:50

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:03:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered '31 Aug 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:57:35

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:03:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Tooth extraction'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:57:35

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:41:40
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'changed from medical history to other as this was not medical history; it occurred after patient enrolled on study and was a dental procedure' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:39:36
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 04:38:29
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 11:48:11
User entered 'Medical History (MH)'	Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:57:35

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:03:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:09:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:33
User entered 'Dental work' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 04:38:29
User entered empty.	Martha Bunnell-Pollak (b) (4)	01 Sep 2020 14:57:35

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:03:24

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered '31 Mar 2021'	Jackie Ziegler (b) (4)	16 Apr 2021 15:32:03
	(b) (4)	

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:03:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User entered 'laminectomy/discectomy L5'	(b) (4) Jackie Ziegler (b) (4)	16 Apr 2021 15:32:03
	(b) (4)	

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:03:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	16 Apr 2021 15:32:15
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	16 Apr 2021 15:32:03
User entered 'Adverse Event (AE)'	Jackie Ziegler (b) (4) (b) (4)	16 Apr 2021 15:32:03

US3852015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:03:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	16 Apr 2021 20:31:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jackie Ziegler (b) (4)	16 Apr 2021 15:32:15
	(b) (4)	
User entered 'back pain'	Jackie Ziegler (b) (4)	16 Apr 2021 15:32:03
	(b) (4)	

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'USA-US076-2020-MRNA-1273-P301000011'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Leland'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Leland'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Allen'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Allen'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'US'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 20:10:52
User entered '4'	System	23 Mar 2021 14:17:58
User entered '3'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
User entered '2'	System	15 Jan 2021 13:20:55
User entered '1'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'USA-US076-2020-MRNA-1273-P301000011'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Leland'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Leland'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Allen'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Allen'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'US'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 20:10:52
User entered '4'	System	23 Mar 2021 14:17:58
User entered '3'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
User entered '2'	System	15 Jan 2021 13:20:55
User entered '1'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:03:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '23/Dec/2020 11:05'	(b) (4) System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:03:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'USA-US076-2020-MRNA-1273-P301000011'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Leland'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Leland'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Allen'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Allen'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'US'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 20:10:52
User entered '4'	System	23 Mar 2021 14:17:58
User entered '3'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
User entered '2'	System	15 Jan 2021 13:20:55
User entered '1'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:03:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '15/Jan/2021 13:20'	(b) (4) System	15 Jan 2021 13:20:55

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:03:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
User entered '1'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:55

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'USA-US076-2020-MRNA-1273-P301000011'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Leland'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Leland'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Allen'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Allen'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'US'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 20:10:52
User entered '4'	System	23 Mar 2021 14:17:58
User entered '3'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
User entered '2'	System	15 Jan 2021 13:20:55
User entered '1'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:03:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:21
User entered '18/Mar/2021 17:41'	System	18 Mar 2021 21:41:20

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:03:24

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.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 21:41:20

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'USA-US076-2020-MRNA-1273-P301000011'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Leland'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Leland'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Allen'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Allen'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'US'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 20:10:52
User entered '4'	System	23 Mar 2021 14:17:58
User entered '3'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
User entered '2'	System	15 Jan 2021 13:20:55
User entered '1'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:03:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:21
User entered '23/Mar/2021 10:17'	System	23 Mar 2021 14:17:58

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:03:24

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.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:18:04
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 14:17:58

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'USA-US076-2020-MRNA-1273-P301000011'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'No (N)'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Leland'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Leland'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:42:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:53:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 21:41:23
Signature has been broken.	System	18 Mar 2021 21:41:20
User entered 'Allen'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
Un-reviewed for Safety.	System	15 Jan 2021 13:20:55
User entered empty.	System	15 Jan 2021 13:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:42
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'Allen'	System	23 Dec 2020 16:05:35

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:53:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:20:42
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:20:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 16:05:51
User entered 'US'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 20:10:52
User entered '4'	System	23 Mar 2021 14:17:58
User entered '3'	System	18 Mar 2021 21:41:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:23:42
	(b) (4)	
User entered '2'	System	15 Jan 2021 13:20:55
User entered '1'	System	23 Dec 2020 16:05:47

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:03:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:13:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 00:08:48
User entered '30/Apr/2021 13:10'	System	30 Apr 2021 20:10:52

US3852015

Folder: SAE USA-US076-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:03:24

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.	Leland Allen (b) (4)	03 May 2021 21:13:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 00:08:48
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 20:10:52

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'USA-US076-2021-MRNA-1273-P301000003'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Leland'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Allen'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
User entered 'US'	System	19 Apr 2021 16:52:39

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 20:28:12
User entered '1'	System	19 Apr 2021 16:52:39

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'USA-US076-2021-MRNA-1273-P301000003'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Leland'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Allen'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
User entered 'US'	System	19 Apr 2021 16:52:39

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 20:28:12
User entered '1'	System	19 Apr 2021 16:52:39

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:03:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
User entered '19/Apr/2021 12:52'	System	19 Apr 2021 16:52:39

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:03:24

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.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 21:44:47
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 16:52:39

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'USA-US076-2021-MRNA-1273-P301000003'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'No (N)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Yes (Y)'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Leland'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:52:33
User entered 'Allen'	System	19 Apr 2021 16:52:18

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:44:47
User entered 'US'	System	19 Apr 2021 16:52:39

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 20:28:12
User entered '1'	System	19 Apr 2021 16:52:39

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:03:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:13:46
User entered '30/Apr/2021 13:28'	(b) (4) System	30 Apr 2021 20:28:12

US3852015

Folder: SAE USA-US076-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:03:24

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.	Leland Allen (b) (4)	03 May 2021 21:13:46
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 20:28:12