

US3802120 (Prod: UPMC University Center)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:29:33

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US3802120

Form: Participant Creation

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

[Participant ID](#)

US3802120

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

US3802120

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Sep 2020 20:32:25

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Sep 2020 20:32:25

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Condition	CATARACTS SURGERY
Start date (dd MMM yyyy)	UN UNK 2015
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Condition	UNDER ACTIVE THYROID
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Condition	R ANKLE FRACTURE
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Condition	MENOPAUSE
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 (6)

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Condition	ELEVATED TRIGLYCERIDES
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 09:39
Height (xxx.x)	60.5 in
Weight (xxx.x)	193 lb
BMI (xxx.x)	37.14980 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 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) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*) 3 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Sep 2020 20:32:25

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

OFFICE WORKER

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) 10 Sep 2020 20:32:25

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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) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 189417

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) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

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) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

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)	3 SEP 2020
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 09:39
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

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)	3 SEP 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 10:41
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
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 10:09 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 10:09

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) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	9:57 (24 HR)
Collection date and time (derived)	3 SEP 2020 9:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:51	3 SEP 2020 09:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 10:42

PC Open Date & Time

03 SEP 2020 10:29

PC Close Date & Time

03 SEP 2020 12:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

03 SEP 2020 21:03

PC Open Date & Time

03 SEP 2020 13:54

PC Close Date & Time

04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 19:15

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

05 SEP 2020 19:22

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

06 SEP 2020 22:50

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:41

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

96.5 °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

09 SEP 2020 07:55

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

98.4 °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

09 SEP 2020 19:37

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

03 SEP 2020 10:43

PC Open Date & Time

03 SEP 2020 10:29

PC Close Date & Time

03 SEP 2020 12:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

03 SEP 2020 21:03

PC Open Date & Time

03 SEP 2020 13:54

PC Close Date & Time

04 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

04 SEP 2020 19:16

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

05 SEP 2020 19:22

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

06 SEP 2020 22:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

07 SEP 2020 20:42

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 07:55

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

09 SEP 2020 19:38

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 10:45
PC Open Date & Time	03 SEP 2020 10:29
PC Close Date & Time	03 SEP 2020 12:59

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 21:04
PC Open Date & Time	03 SEP 2020 13:54
PC Close Date & Time	04 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:17
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

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 ☒

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:23
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

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 ☒

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:53
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

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 ☒

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 20:42
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 07:56
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

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 ☒

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:38
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3802120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PARTICIPANT CONTACTED
AND LEFT MESSAGE 3 TIMES
WITHIN CONTACT WINDOW.
PARTICIPANT CALLED BACK 1
DAY OUTSIDE OF WINDOW.

US3802120

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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	VISIT2

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 16:32:51

Generated On: 12 Aug 2021 13:29:33

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)	2 OCT 2020
Time of assessment (00:00-23:59)	09:02 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 09:02
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	168 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 16:32:51

Generated On: 12 Aug 2021 13:29:33

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)	2 OCT 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:00
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
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3802120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

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.

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 09:29 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 09:29

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

US3802120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 OCT 2020

Collection time (00:00-23:59)

09:25 (24 HR)

Collection date and time (derived)

2 OCT 2020 09:25

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:20	2 OCT 2020 09:20
Nasopharyngeal Swab 2	No		

US3802120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

02 OCT 2020 10:05

PC Open Date & Time

02 OCT 2020 09:49

PC Close Date & Time

02 OCT 2020 12:19

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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 96.8 °F

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

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

PC Time Stamp	02 OCT 2020 23:02
PC Open Date & Time	02 OCT 2020 13:14
PC Close Date & Time	03 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

03 OCT 2020 23:56

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

04 OCT 2020 23:11

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 19:27

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 21:19

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 19:34

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

08 OCT 2020 22:26

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 10:05

PC Open Date & Time

02 OCT 2020 09:49

PC Close Date & Time

02 OCT 2020 12:19

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

02 OCT 2020 23:06

PC Open Date & Time

02 OCT 2020 13:14

PC Close Date & Time

03 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

03 OCT 2020 23:58

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

04 OCT 2020 23:11

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

05 OCT 2020 19:27

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

06 OCT 2020 21:20

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

07 OCT 2020 19:35

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

08 OCT 2020 22:26

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 10:06
PC Open Date & Time	02 OCT 2020 09:49
PC Close Date & Time	02 OCT 2020 12:19

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 23:07
PC Open Date & Time	02 OCT 2020 13:14
PC Close Date & Time	03 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

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 ☒

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 23:58
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

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 ☒

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 23:12
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

98 of 2509

EAB) (1725)

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:28
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2509

EAB) (1725)

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 21:20
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

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 ☒

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 19:35
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

104 of 2509

EAB) (1725)

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 22:27
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3802120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

ATTEMPTED THREE TIMES

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 NOV 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

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 NOV 2020
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	3 NOV 2020 08:54
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

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.

US3802120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 NOV 2020

Collection time (00:00-23:59)

09:10 (24 HR)

Collection date and time (derived)

3 NOV 2020 09:10

US3802120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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°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"/>

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 117

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 145

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 166

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 173

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 194

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 16:01:41

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

27 MAR 2021 08:53:30

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

05 APR 2021 08:58:00

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 18:35:50

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

17 APR 2021 22:39:24

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 12:19:58

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

02 MAY 2021 23:07:46

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 <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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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°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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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="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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 285

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 306

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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°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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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="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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 327

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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°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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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°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="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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 425

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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="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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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="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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 614

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 621

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 670

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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="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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 726

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 747

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

DAY 796

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

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

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

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

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

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

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 ☐

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3802120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:29:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		23 MAR 2021 16:02:14

US3802120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:30:44

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 16:32:51

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 16:32:51

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:59:13

Generated On: 12 Aug 2021 13:29:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 19:47:57

Generated On: 12 Aug 2021 13:29:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:11 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 14:11
Temperature (<i>xxx.x</i>)	97.8 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>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:59:13

Generated On: 12 Aug 2021 13:29:33

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.

US3802120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:59:13

Generated On: 12 Aug 2021 13:29:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

14:18 (24 HR)

Collection date and time (derived)

23 MAR 2021 14:18

US3802120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:59:13

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 Feb 2021 16:11:28

Generated On: 12 Aug 2021 13:29:33

Date of Contact	15 JAN 2021
Time of Contact	12:13
Date and Time of Contact (derived)	15 JAN 2021 12:13
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021
------	-------------

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

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

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

Temperature	97.6 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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"/>

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Symptom Day

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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"/>

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021
------	-------------

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

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

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021
------	-------------

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

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

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

Temperature	97.6 F
-------------	--------

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

Cough	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" 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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US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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"/>

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021
------	-------------

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

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

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 15 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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"/>

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

	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"/>

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

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 ☐

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Feb 2021 16:11:28

Generated On: 12 Aug 2021 13:29:33

Date of Visit	15 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	15 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Feb 2021 16:11:28

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Feb 2021 16:11:28

Generated On: 12 Aug 2021 13:29:33

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

16 JAN 2021

End Date

16 JAN 2021

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Feb 2021 16:11:28

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Feb 2021 16:11:28

Generated On: 12 Aug 2021 13:29:33

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3802120

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 16:30:24

Generated On: 12 Aug 2021 13:29:33

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	17 JAN 2021
Day 5	Yes	19 JAN 2021
Day 7	Yes	21 JAN 2021
Day 9	Yes	23 JAN 2021
Day 14	Yes	28 JAN 2021
Day 21	Yes	04 FEB 2021
Day 28	Yes	17 FEB 2021

US3802120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 12:13
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:11:28

Generated On: 12 Aug 2021 13:29:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3802120

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 16:30:24

Generated On: 12 Aug 2021 13:29:33

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 JAN 2021

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

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	SICKD28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

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)	11:17 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 11:17
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

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.

US3802120

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 FEB 2021

US3802120

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

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

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

Visit date (dd MMM yyyy)	7 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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US3802120

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 18:38:05

Generated On: 12 Aug 2021 13:29:33

Date of updated informed consent (<i>dd MMM yyyy</i>)	7 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>)	7 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

US3802120

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Height	60 in
Weight	191 lb
BMI (xxx.x)	37.38013

US3802120

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Height	60 in
Weight	191 lb
BMI (xxx.x)	37.38013
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)	7 JAN 2021
Time of assessment (00:00-23:59)	10:33 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 10:33
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3802120

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Height	60 in
Weight	191 lb
BMI (xxx.x)	37.38013
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)	7 JAN 2021
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 12:20
Temperature (xxx.x)	99.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3802120

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

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 JAN 2021

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

US3802120

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

Form: Exposure

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

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) 7 JAN 2021

What was the treatment time? (00:00-23:59) 11:38 (24 HR)

Treatment Date and Time (derived) 7 JAN 2021 11:38

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

US3802120

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 JAN 2021

Collection time (00:00-23:59)

11:05 (24 HR)

Collection date and time (derived)

7 JAN 2021 11:05

US3802120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	11:08
Collection Date and Time (derived)	7 JAN 2021 11:08

US3802120

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

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:39

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:11:40

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

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)	11:17 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 11:17
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 12:41
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	INFRARED
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3802120

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

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.

US3802120

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

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) 12:13 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 12:13

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

US3802120

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 16:32:51

Generated On: 12 Aug 2021 13:29:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPTED THREE TIMES AND
LEFT TWO MESSAGES.

If Contact Not Made, please provide Comments

US3802120

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 16:32:51

Generated On: 12 Aug 2021 13:29:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802120

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:59:13

Generated On: 12 Aug 2021 13:29:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 17:59:13

Generated On: 12 Aug 2021 13:29:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:11 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 14:11
Temperature (<i>xxx.x</i>)	97.8 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>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802120

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:59:13

Generated On: 12 Aug 2021 13:29:33

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.

US3802120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:59:13

Generated On: 12 Aug 2021 13:29:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

14:18 (24 HR)

Collection date and time (derived)

23 MAR 2021 14:18

US3802120

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 14:45:22

Generated On: 12 Aug 2021 13:29:33

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 19:47:57

Generated On: 12 Aug 2021 13:29:33

AEID	USA-US098-2021-MRNA-1273-P30 1000002
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)	15 JAN 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)	20 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) 31 Mar 2021 19:47:57

Generated On: 12 Aug 2021 13:29:33

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

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

Yes ☒

No ☐

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

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:48:59

Generated On: 12 Aug 2021 13:29:33

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication ELEVATED TRIGLYCERIDES

Dose per administration 145

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:48:59

Generated On: 12 Aug 2021 13:29:33

	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 2008	
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"/>

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:48:59

Generated On: 12 Aug 2021 13:29:33

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 100

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

439 of 2509

EAB) (1725)

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:48:59

Generated On: 12 Aug 2021 13:29:33

	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 1985
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"/>

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:48:59

Generated On: 12 Aug 2021 13:29:33

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:48:59

Generated On: 12 Aug 2021 13:29:33

	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"/>

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:48:59

Generated On: 12 Aug 2021 13:29:33

Name of Medication ADVIL (IBUPROFEN)

Prophylaxis Yes ☐
No ☒

Indication FEVER DUE TO SYMPTOMATIC
COVID

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:48:59

Generated On: 12 Aug 2021 13:29:33

	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)		15 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 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"/>

US3802120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 12:30:43

Generated On: 12 Aug 2021 13:29:33

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3802120

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

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

US3802120

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 10 Sep 2020 20:32:25

Generated On: 12 Aug 2021 13:29:33

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 19:12:30

Generated On: 12 Aug 2021 13:29:33

SAEID	USA-US098-2021-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 19:12:30

Generated On: 12 Aug 2021 13:29:33

SAEID	USA-US098-2021-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/FEB/2021 14:42
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

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 19:12:30

Generated On: 12 Aug 2021 13:29:33

SAEID	USA-US098-2021-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/MAR/2021 09:41
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

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 19:12:30

Generated On: 12 Aug 2021 13:29:33

SAEID	USA-US098-2021-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	31/MAR/2021 09:39
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

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Apr 2021 19:12:30

Generated On: 12 Aug 2021 13:29:33

SAEID	USA-US098-2021-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/APR/2021 09:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3802120 (Prod: UPMC University Center)

US3802120

Form: Participant Creation

Generated On: 12 Aug 2021 13:29:33

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:05:52
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'US3802120'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 13:25:09

US3802120

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:28:51

US3802120

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 13:25:10

US3802120

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:28:51

US3802120

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'SCRN'	System	03 Sep 2020 13:28:51

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered (b) (6) 1944'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 13:25:11

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '76'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'YEARS'	System	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '76'	System	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Female (F)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'I'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:29:33

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:09

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'Sep 2020'	System	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '2020'	System	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Amendment 3 (3)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:22

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 13:25:10

US3802120

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:29:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'I'	System	03 Sep 2020 13:29:26

US3802120

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:29:33

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:26

US3802120

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:29:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:07:33

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:09:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:09:39
Data point term sent to Coder	System	03 Sep 2020 14:08:50
User entered 'Cataracts Surgery'	Dominic Kramer (b) (4)	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'UN UNK 2015'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '0'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'I'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'Jan 2015'	System	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '2015'	System	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:29:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	03 Sep 2020 14:08:06

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 15:33:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 15:33:39
Data point term sent to Coder	System	03 Sep 2020 14:08:50
User entered 'Under active thyroid'	Dominic Kramer (b) (4)	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'UN UNK 1985'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '0'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'Jan 1985'	System	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '1985'	System	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:29:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	03 Sep 2020 14:08:38

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 14:10:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 14:10:41
Data point term sent to Coder	System	03 Sep 2020 14:09:53
User entered 'R Ankle Fracture'	Dominic Kramer (b) (4)	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'UN UNK 2018'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'I'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'Jan 2018'	System	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '2018'	System	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:29:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	03 Sep 2020 14:09:35

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:11:46
Data point term sent to Coder	System	03 Sep 2020 14:10:54
User entered 'GERD'	Dominic Kramer (b) (4)	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'UN UNK 2019'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered empty.	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'Jan 2019'	System	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '2019'	System	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:29:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	03 Sep 2020 14:10:33

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 19:46:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 19:46:38
Data point term sent to Coder	System	22 Oct 2020 19:45:42
User entered 'Menopause'	Emily Carney (b) (4)	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Emily Carney (b) (4) (b) (4)	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'I'	(b) (4) Emily Carney (b) (4) (b) (4)	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Carney (b) (4)	22 Oct 2020 19:45:21
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4)	22 Oct 2020 19:45:08
User entered 'Yes (Y)'	Emily Carney (b) (4)	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered empty.	(b) (4) Emily Carney (b) (4)	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	22 Oct 2020 19:45:21
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	22 Oct 2020 19:45:08
User entered '0'	(b) (4)	
	Emily Carney (b) (4)	22 Oct 2020 19:44:58
	(b) (4)	

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:29:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	22 Oct 2020 19:44:58

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Triglyceride analyses, PT: Blood triglycerides increased, LLT: Triglyceride increased - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 21:16:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 21:16:33
Data point term sent to Coder	System	13 Nov 2020 20:59:38
User entered 'elevated triglycerides'	Melissa Andrasko (b) (4)	13 Nov 2020 20:58:51
	(b) (4)	

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'UN UNK 2008'	Melissa Andrasko (b) (4) (b) (4)	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '0'	Melissa Andrasko (b) (4) (b) (4)	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Melissa Andrasko (b) (4) (b) (4)	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Melissa Andrasko (b) (4) (b) (4)	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '0'	Melissa Andrasko (b) (4) (b) (4)	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'Jan 2008'	System	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '2008'	System	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:29:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered empty.	System	13 Nov 2020 20:58:51

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '09:39'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '3 Sep 2020 09:39'	System	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '60.5' in	(b) (4)	
	Dominic Kramer (b) (4)	03 Sep 2020 14:12:32
	(b) (4)	
DataPoint set to visible.	System	03 Sep 2020 13:29:26

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '193' lb	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:12:32
DataPoint set to visible.	(b) (4) System	03 Sep 2020 13:29:26

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered '37.14980'	System	03 Sep 2020 14:12:32
DataPoint set to visible.	System	03 Sep 2020 13:29:26

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'kg/m2'	System	03 Sep 2020 14:12:32
DataPoint set to visible.	System	03 Sep 2020 13:29:26

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '97.2' F	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '55'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'bpm'	System	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '18'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'breaths/min'	System	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '167'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'mmHg'	System	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '69'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User entered 'mmHg'	System	03 Sep 2020 14:12:32

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16

US3802120

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16

US3802120

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:36

US3802120

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:29:36

US3802120

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:02

US3802120

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:29:33

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:02

US3802120

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:29:33

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		29 Oct 2020 16:23:36
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'recorded in medical history ' (Site from DM).	Emily Carney (b) (4) (b) (4)	22 Oct 2020 19:44:24
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 06:17:59
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:30:02

US3802120

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:29:33

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:02

US3802120

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:02

US3802120

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:29:33

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:02

US3802120

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:02

US3802120

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:29:33

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'I'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:02

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:13:10

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Folder: Screening

Form: Risk of Exposure

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[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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

[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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Office Worker'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '0'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

[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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '0'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

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)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '0'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:29:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:54:16
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered empty.	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:10

US3802120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:38

US3802120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:30:38

US3802120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

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 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:30:38

US3802120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'VISIT1'	System	03 Sep 2020 13:30:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 13:39:56

US3802120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '189417'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 13:39:56

US3802120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 13:39:56

US3802120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

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 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:41:08

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

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 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:41:08

US3802120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:41:08

US3802120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 13:41:08

US3802120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 13:41:08

US3802120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:29:33

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 08:53:05
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Per medical history this participant is HIV negative.' (Site from DM).	Emily Carney (b) (4) (b) (4)	07 Jan 2021 15:32:34
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 15:32:26
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 18:57:12
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:06:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:06:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:01:02
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' answered with 'Nd added' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:11
Signature has been broken.	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:03
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:32:53
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '60.5' in	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
Signature has been broken.	(b) (4)	
	Jennifer Nagg (b) (4)	16 Oct 2020 01:38:03
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jennifer Nagg (b) (4)	16 Oct 2020 01:38:03
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
	(b) (4)	
User entered '193' lb	Lalicia Roman (b) (4)	03 Sep 2020 15:31:43
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:01:02
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' answered with 'Nd added' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:11
Signature has been broken.	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:03
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:32:53
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '60.5' in	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
Signature has been broken.	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:03
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '193' lb	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User accepted default value 'Pre-Dose (PREDOSE)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '09:39'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '3 Sep 2020 09:39'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '97.2' F	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '55'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'bpm'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '18'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'breaths/min'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 05:50:12
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'actual BP NCS' (Site from System).		08 Sep 2020 13:56:37
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	03 Sep 2020 15:31:43
User entered '167'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '69'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:01:02
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' answered with 'Nd added' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:11
Signature has been broken.	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 01:38:03
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update 'ND' accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:32:53
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '60.5' in	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
Signature has been broken.	(b) (4)	
	Jennifer Nagg (b) (4)	16 Oct 2020 01:38:03
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jennifer Nagg (b) (4)	16 Oct 2020 01:38:03
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
	(b) (4)	
User entered '193' lb	Lalicia Roman (b) (4)	03 Sep 2020 15:31:43
	(b) (4)	

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User accepted default value 'Post-Dose (POSTDOSE)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '10:41'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '3 Sep 2020 10:41'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '97.7' F	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Other (Other)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'infrared'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '51'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'bpm'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '16'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'breaths/min'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '147'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '67'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	03 Sep 2020 15:31:43

US3802120

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 14:11:21

US3802120

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 14:11:21

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

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 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '10:09'	(b) (4) Lalicia Roman (b) (4)	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '3 Sep 2020 10:09'	System	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'ONCE'	System	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 14:11:05

US3802120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:50

US3802120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:50

US3802120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '9:57'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:13:50

US3802120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '3 Sep 2020 9:57'	System	03 Sep 2020 14:13:50

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:29:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '3 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:29:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered '09:51'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '3 Sep 2020 09:51'	System	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:29:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered empty.	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered empty.	System	03 Sep 2020 14:14:19

US3802120

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:19:24

US3802120

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '1'	System	03 Sep 2020 14:19:24

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:42:06', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f23ef338-2bda-4e24-948f-38d98e28dd49'	System	03 Sep 2020 14:42:47
User entered 'Yes (Y)'	System	03 Sep 2020 14:42:47

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:42:21', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f23ef338-2bda-4e24-948f-38d98e28dd49' User entered '97.7'	System	03 Sep 2020 14:42:47
	System	03 Sep 2020 14:42:47

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:42:31', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f23ef338-2bda-4e24-948f-38d98e28dd49'	System	03 Sep 2020 14:42:47
User entered 'No (N)'	System	03 Sep 2020 14:42:47

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:42:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f23ef338-2bda-4e24-948f-38d98e28dd49'	System	03 Sep 2020 14:42:47
User entered '03 Sep 2020 10:42'	System	03 Sep 2020 14:42:47

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 10:29'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 12:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:02:20', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '33be8ff0-41b3-4097-a173-936259965d2c' User entered 'Yes (Y)'	System	04 Sep 2020 01:03:15
	System	04 Sep 2020 01:03:15

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:02:34', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '33be8ff0-41b3-4097-a173-936259965d2c' User entered '97.7'	System	04 Sep 2020 01:03:15
	System	04 Sep 2020 01:03:15

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:02:41', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '33be8ff0-41b3-4097-a173-936259965d2c'	System	04 Sep 2020 01:03:15
User entered 'No (N)'	System	04 Sep 2020 01:03:15

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:03:10', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '33be8ff0-41b3-4097-a173-936259965d2c' User entered '03 Sep 2020 21:03'	System	04 Sep 2020 01:03:15
	System	04 Sep 2020 01:03:15

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 13:54'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 2'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:15:27', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8f78f628-8d3e-41cf-a20b-5e0d9484331c' User entered 'Yes (Y)'	System	04 Sep 2020 23:15:53
	System	04 Sep 2020 23:15:53

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:15:36', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8f78f628-8d3e-41cf-a20b-5e0d9484331c' User entered '97.8'	System	04 Sep 2020 23:15:53
	System	04 Sep 2020 23:15:53

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:15:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8f78f628-8d3e-41cf-a20b-5e0d9484331c'	System	04 Sep 2020 23:15:53
User entered 'No (N)'	System	04 Sep 2020 23:15:53

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:15:52', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8f78f628-8d3e-41cf-a20b-5e0d9484331c' User entered '04 Sep 2020 19:15'	System	04 Sep 2020 23:15:53
	System	04 Sep 2020 23:15:53

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 3'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:21:52', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '45abf7bd-26c1-4c91-af02-64eb452fc9a1' User entered 'Yes (Y)'	System	05 Sep 2020 23:22:20
	System	05 Sep 2020 23:22:20

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:22:04', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '45abf7bd-26c1-4c91-af02-64eb452fc9a1' User entered '97.5'	System	05 Sep 2020 23:22:20
	System	05 Sep 2020 23:22:20

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:22:11', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '45abf7bd-26c1-4c91-af02-64eb452fc9a1' User entered 'No (N)'	System	05 Sep 2020 23:22:20
	System	05 Sep 2020 23:22:20

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:22:16', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '45abf7bd-26c1-4c91-af02-64eb452fc9a1' User entered '05 Sep 2020 19:22'	System	05 Sep 2020 23:22:20
	System	05 Sep 2020 23:22:20

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 4'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:50:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '2175b90c-87b9-4cd5-9dc6-00e053f1c9f3'	System	07 Sep 2020 02:50:26
User entered 'Yes (Y)'	System	07 Sep 2020 02:50:26

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:50:11', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '2175b90c-87b9-4cd5-9dc6-00e053f1c9f3' User entered '97.4'	System	07 Sep 2020 02:50:26
	System	07 Sep 2020 02:50:26

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:50:17', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '2175b90c-87b9-4cd5-9dc6-00e053f1c9f3'	System	07 Sep 2020 02:50:26
User entered 'No (N)'	System	07 Sep 2020 02:50:26

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:50:24', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '2175b90c-87b9-4cd5-9dc6-00e053f1c9f3'	System	07 Sep 2020 02:50:26
User entered '06 Sep 2020 22:50'	System	07 Sep 2020 02:50:26

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 5'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:41:07', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8a92ff87-90cb-41a2-8763-2493315f19b7'	System	08 Sep 2020 00:41:28
User entered 'Yes (Y)'	System	08 Sep 2020 00:41:28

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:41:13', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8a92ff87-90cb-41a2-8763-2493315f19b7' User entered '98.6'	System	08 Sep 2020 00:41:28
	System	08 Sep 2020 00:41:28

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:41:19', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8a92ff87-90cb-41a2-8763-2493315f19b7'	System	08 Sep 2020 00:41:28
User entered 'No (N)'	System	08 Sep 2020 00:41:28

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:41:26', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8a92ff87-90cb-41a2-8763-2493315f19b7' User entered '07 Sep 2020 20:41'	System	08 Sep 2020 00:41:28
	System	08 Sep 2020 00:41:28

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 6'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:54:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'bfabcd12-e571-42ef-9993-c4d92c75d38d' User entered 'Yes (Y)'	System	09 Sep 2020 11:55:07
	System	09 Sep 2020 11:55:07

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:54:52', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'bfabcd12-e571-42ef-9993-c4d92c75d38d' User entered '96.5'	System	09 Sep 2020 11:55:07
	System	09 Sep 2020 11:55:07

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:54:57', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'bfabcd12-e571-42ef-9993-c4d92c75d38d' User entered 'No (N)'	System	09 Sep 2020 11:55:07
	System	09 Sep 2020 11:55:07

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:04', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'bfabcd12-e571-42ef-9993-c4d92c75d38d' User entered '09 Sep 2020 07:55'	System	09 Sep 2020 11:55:07
	System	09 Sep 2020 11:55:07

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 7'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:37:39', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'a1223d77-aff4-46c4-b29c-f88927fcb607' User entered 'Yes (Y)'	System	09 Sep 2020 23:38:01
	System	09 Sep 2020 23:38:01

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:37:46', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'a1223d77-aff4-46c4-b29c-f88927fcb607' User entered '98.4'	System	09 Sep 2020 23:38:01
	System	09 Sep 2020 23:38:01

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:37:51', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'a1223d77-aff4-46c4-b29c-f88927fcb607'	System	09 Sep 2020 23:38:01
User entered 'No (N)'	System	09 Sep 2020 23:38:01

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:37:58', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'a1223d77-aff4-46c4-b29c-f88927fcb607' User entered '09 Sep 2020 19:37'	System	09 Sep 2020 23:38:01
	System	09 Sep 2020 23:38:01

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:43:27', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6aaf1eb-4851-4d74-92a4-e2fa920f7234'	System	03 Sep 2020 14:43:58
User entered 'None (1)'	System	03 Sep 2020 14:43:58

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:43:33', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6aaf1eb-4851-4d74-92a4-e2fa920f7234' User entered 'No (N)'	System	03 Sep 2020 14:43:58
	System	03 Sep 2020 14:43:58

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:43:39', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6aaf1eb-4851-4d74-92a4-e2fa920f7234' User entered 'No (N)'	System	03 Sep 2020 14:43:58
	System	03 Sep 2020 14:43:58

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:43:46', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6aaf1eb-4851-4d74-92a4-e2fa920f7234'	System	03 Sep 2020 14:43:58
User entered 'None (1)'	System	03 Sep 2020 14:43:58

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:43:53', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6aaf1eb-4851-4d74-92a4-e2fa920f7234' User entered '03 Sep 2020 10:43'	System	03 Sep 2020 14:43:58
	System	03 Sep 2020 14:43:58

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 10:29'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 12:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:03:19', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '82a7443f-ce53-4c79-9a27-7803da785548'	System	04 Sep 2020 01:03:48
User entered 'None (1)'	System	04 Sep 2020 01:03:48

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:03:30', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '82a7443f-ce53-4c79-9a27-7803da785548' User entered 'No (N)'	System	04 Sep 2020 01:03:48
	System	04 Sep 2020 01:03:48

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:03:35', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '82a7443f-ce53-4c79-9a27-7803da785548' User entered 'No (N)'	System	04 Sep 2020 01:03:48
	System	04 Sep 2020 01:03:48

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:03:41', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '82a7443f-ce53-4c79-9a27-7803da785548'	System	04 Sep 2020 01:03:48
User entered 'None (1)'	System	04 Sep 2020 01:03:48

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:03:46', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '82a7443f-ce53-4c79-9a27-7803da785548' User entered '03 Sep 2020 21:03'	System	04 Sep 2020 01:03:48
	System	04 Sep 2020 01:03:48

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 13:54'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 2'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:16:26', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '22fef5a2-544c-44fb-9d2d-b4d7590c9f50'	System	04 Sep 2020 23:16:50
User entered 'None (1)'	System	04 Sep 2020 23:16:50

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:16:32', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '22fef5a2-544c-44fb-9d2d-b4d7590c9f50'	System	04 Sep 2020 23:16:50
User entered 'No (N)'	System	04 Sep 2020 23:16:50

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:16:39', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '22fef5a2-544c-44fb-9d2d-b4d7590c9f50'	System	04 Sep 2020 23:16:50
User entered 'No (N)'	System	04 Sep 2020 23:16:50

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:16:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '22fef5a2-544c-44fb-9d2d-b4d7590c9f50'	System	04 Sep 2020 23:16:50
User entered 'None (1)'	System	04 Sep 2020 23:16:50

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:16:48', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '22fef5a2-544c-44fb-9d2d-b4d7590c9f50'	System	04 Sep 2020 23:16:50
User entered '04 Sep 2020 19:16'	System	04 Sep 2020 23:16:50

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 3'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:22:37', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '93211060-7be8-45cf-ab7a-88bec46f961e'	System	05 Sep 2020 23:22:59
User entered 'None (1)'	System	05 Sep 2020 23:22:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:22:42', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '93211060-7be8-45cf-ab7a-88bec46f961e' User entered 'No (N)'	System	05 Sep 2020 23:22:59
	System	05 Sep 2020 23:22:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:22:46', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '93211060-7be8-45cf-ab7a-88bec46f961e' User entered 'No (N)'	System	05 Sep 2020 23:22:59
	System	05 Sep 2020 23:22:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:22:51', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '93211060-7be8-45cf-ab7a-88bec46f961e' User entered 'None (1)'	System	05 Sep 2020 23:22:59
	System	05 Sep 2020 23:22:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:22:55', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '93211060-7be8-45cf-ab7a-88bec46f961e' User entered '05 Sep 2020 19:22'	System	05 Sep 2020 23:22:59
	System	05 Sep 2020 23:22:59

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 4'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:50:33', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03b6e65c-eede-4192-b80e-35802f7f2875'	System	07 Sep 2020 02:51:27
User entered 'None (1)'	System	07 Sep 2020 02:51:27

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:50:37', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03b6e65c-eede-4192-b80e-35802f7f2875' User entered 'No (N)'	System	07 Sep 2020 02:51:27
	System	07 Sep 2020 02:51:27

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:50:43', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03b6e65c-eede-4192-b80e-35802f7f2875'	System	07 Sep 2020 02:51:27
User entered 'No (N)'	System	07 Sep 2020 02:51:27

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:50:48', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03b6e65c-eede-4192-b80e-35802f7f2875'	System	07 Sep 2020 02:51:27
User entered 'None (1)'	System	07 Sep 2020 02:51:27

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:51:25', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03b6e65c-eede-4192-b80e-35802f7f2875' User entered '06 Sep 2020 22:51'	System	07 Sep 2020 02:51:27
	System	07 Sep 2020 02:51:27

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 5'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:41:39', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '406e2591-85cb-4034-8c0a-70c4aa49e26c'	System	08 Sep 2020 00:42:04
User entered 'None (1)'	System	08 Sep 2020 00:42:04

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:41:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '406e2591-85cb-4034-8c0a-70c4aa49e26c' User entered 'No (N)'	System	08 Sep 2020 00:42:04
	System	08 Sep 2020 00:42:04

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:41:48', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '406e2591-85cb-4034-8c0a-70c4aa49e26c' User entered 'No (N)'	System	08 Sep 2020 00:42:04
	System	08 Sep 2020 00:42:04

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:41:55', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '406e2591-85cb-4034-8c0a-70c4aa49e26c'	System	08 Sep 2020 00:42:04
User entered 'None (1)'	System	08 Sep 2020 00:42:04

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '406e2591-85cb-4034-8c0a-70c4aa49e26c' User entered '07 Sep 2020 20:42'	System	08 Sep 2020 00:42:04
	System	08 Sep 2020 00:42:04

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 6'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:12', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8636da53-150b-4710-bc1e-ac28e304cd35'	System	09 Sep 2020 11:55:30
User entered 'None (1)'	System	09 Sep 2020 11:55:30

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:16', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8636da53-150b-4710-bc1e-ac28e304cd35'	System	09 Sep 2020 11:55:30
User entered 'No (N)'	System	09 Sep 2020 11:55:30

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:19', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8636da53-150b-4710-bc1e-ac28e304cd35'	System	09 Sep 2020 11:55:30
User entered 'No (N)'	System	09 Sep 2020 11:55:30

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:23', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8636da53-150b-4710-bc1e-ac28e304cd35' User entered 'None (1)'	System	09 Sep 2020 11:55:30
	System	09 Sep 2020 11:55:30

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:28', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8636da53-150b-4710-bc1e-ac28e304cd35' User entered '09 Sep 2020 07:55'	System	09 Sep 2020 11:55:30
	System	09 Sep 2020 11:55:30

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 7'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:04', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '73981d17-6064-4adf-bad6-3ca3d2a1907c'	System	09 Sep 2020 23:38:23
User entered 'None (1)'	System	09 Sep 2020 23:38:23

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:08', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '73981d17-6064-4adf-bad6-3ca3d2a1907c' User entered 'No (N)'	System	09 Sep 2020 23:38:23
	System	09 Sep 2020 23:38:23

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:11', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '73981d17-6064-4adf-bad6-3ca3d2a1907c' User entered 'No (N)'	System	09 Sep 2020 23:38:23
	System	09 Sep 2020 23:38:23

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:16', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '73981d17-6064-4adf-bad6-3ca3d2a1907c' User entered 'None (1)'	System	09 Sep 2020 23:38:23
	System	09 Sep 2020 23:38:23

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:21', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '73981d17-6064-4adf-bad6-3ca3d2a1907c' User entered '09 Sep 2020 19:38'	System	09 Sep 2020 23:38:23
	System	09 Sep 2020 23:38:23

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:44:06', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '190240fa-3ba1-4876-bbff-167697bf4c9a' User entered 'None (0)'	System	03 Sep 2020 14:45:18
	System	03 Sep 2020 14:45:18

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:44:17', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '190240fa-3ba1-4876-bbff-167697bf4c9a' User entered 'None (0)'	System	03 Sep 2020 14:45:18
	System	03 Sep 2020 14:45:18

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:44:22', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '190240fa-3ba1-4876-bbff-167697bf4c9a' User entered 'None (0)'	System	03 Sep 2020 14:45:18
	System	03 Sep 2020 14:45:18

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:44:27', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '190240fa-3ba1-4876-bbff-167697bf4c9a' User entered 'None (0)'	System	03 Sep 2020 14:45:18
	System	03 Sep 2020 14:45:18

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:44:56', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '190240fa-3ba1-4876-bbff-167697bf4c9a' User entered 'None (0)'	System	03 Sep 2020 14:45:18
	System	03 Sep 2020 14:45:18

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:45:02', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '190240fa-3ba1-4876-bbff-167697bf4c9a' User entered 'None (0)'	System	03 Sep 2020 14:45:18
	System	03 Sep 2020 14:45:18

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:45:11', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '190240fa-3ba1-4876-bbff-167697bf4c9a'	System	03 Sep 2020 14:45:18
User entered 'No (N)'	System	03 Sep 2020 14:45:18

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T10:45:16', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '190240fa-3ba1-4876-bbff-167697bf4c9a' User entered '03 Sep 2020 10:45'	System	03 Sep 2020 14:45:18
	System	03 Sep 2020 14:45:18

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 10:29'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 12:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:03:53', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03f7efd8-6823-4e16-9281-24b358f038ca' User entered 'None (0)'	System	04 Sep 2020 01:04:46
	System	04 Sep 2020 01:04:46

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:03:57', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03f7efd8-6823-4e16-9281-24b358f038ca' User entered 'None (0)'	System	04 Sep 2020 01:04:46
	System	04 Sep 2020 01:04:46

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:04:02', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03f7efd8-6823-4e16-9281-24b358f038ca' User entered 'None (0)'	System	04 Sep 2020 01:04:46
	System	04 Sep 2020 01:04:46

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:04:06', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03f7efd8-6823-4e16-9281-24b358f038ca' User entered 'None (0)'	System	04 Sep 2020 01:04:46
	System	04 Sep 2020 01:04:46

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:04:10', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03f7efd8-6823-4e16-9281-24b358f038ca' User entered 'None (0)'	System	04 Sep 2020 01:04:46
	System	04 Sep 2020 01:04:46

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:04:13', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03f7efd8-6823-4e16-9281-24b358f038ca' User entered 'None (0)'	System	04 Sep 2020 01:04:46
	System	04 Sep 2020 01:04:46

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:04:24', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03f7efd8-6823-4e16-9281-24b358f038ca' User entered 'No (N)'	System	04 Sep 2020 01:04:46
	System	04 Sep 2020 01:04:46

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-03T21:04:45', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '03f7efd8-6823-4e16-9281-24b358f038ca' User entered '03 Sep 2020 21:04'	System	04 Sep 2020 01:04:46
	System	04 Sep 2020 01:04:46

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Sep 2020 13:54'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 2'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:17:12', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd2126a73-2727-47e0-9cb1-2748b329a92c' User entered 'None (0)'	System	04 Sep 2020 23:17:52
	System	04 Sep 2020 23:17:52

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:17:17', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd2126a73-2727-47e0-9cb1-2748b329a92c' User entered 'None (0)'	System	04 Sep 2020 23:17:52
	System	04 Sep 2020 23:17:52

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:17:21', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd2126a73-2727-47e0-9cb1-2748b329a92c' User entered 'None (0)'	System	04 Sep 2020 23:17:52
	System	04 Sep 2020 23:17:52

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:17:27', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd2126a73-2727-47e0-9cb1-2748b329a92c' User entered 'None (0)'	System	04 Sep 2020 23:17:52
	System	04 Sep 2020 23:17:52

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:17:30', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd2126a73-2727-47e0-9cb1-2748b329a92c' User entered 'None (0)'	System	04 Sep 2020 23:17:52
	System	04 Sep 2020 23:17:52

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:17:33', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd2126a73-2727-47e0-9cb1-2748b329a92c' User entered 'None (0)'	System	04 Sep 2020 23:17:52
	System	04 Sep 2020 23:17:52

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:17:43', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd2126a73-2727-47e0-9cb1-2748b329a92c' User entered 'No (N)'	System	04 Sep 2020 23:17:52
	System	04 Sep 2020 23:17:52

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-04T19:17:49', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd2126a73-2727-47e0-9cb1-2748b329a92c' User entered '04 Sep 2020 19:17'	System	04 Sep 2020 23:17:52
	System	04 Sep 2020 23:17:52

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 3'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:23:09', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '09442a72-055d-46df-bab2-4b984dca76b3' User entered 'None (0)'	System	05 Sep 2020 23:23:45
	System	05 Sep 2020 23:23:45

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:23:12', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '09442a72-055d-46df-bab2-4b984dca76b3' User entered 'None (0)'	System	05 Sep 2020 23:23:45
	System	05 Sep 2020 23:23:45

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:23:17', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '09442a72-055d-46df-bab2-4b984dca76b3' User entered 'None (0)'	System	05 Sep 2020 23:23:45
	System	05 Sep 2020 23:23:45

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:23:22', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '09442a72-055d-46df-bab2-4b984dca76b3' User entered 'None (0)'	System	05 Sep 2020 23:23:45
	System	05 Sep 2020 23:23:45

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:23:25', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '09442a72-055d-46df-bab2-4b984dca76b3' User entered 'None (0)'	System	05 Sep 2020 23:23:45
	System	05 Sep 2020 23:23:45

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:23:28', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '09442a72-055d-46df-bab2-4b984dca76b3' User entered 'None (0)'	System	05 Sep 2020 23:23:45
	System	05 Sep 2020 23:23:45

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:23:35', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '09442a72-055d-46df-bab2-4b984dca76b3' User entered 'No (N)'	System	05 Sep 2020 23:23:45
	System	05 Sep 2020 23:23:45

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-05T19:23:39', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '09442a72-055d-46df-bab2-4b984dca76b3' User entered '05 Sep 2020 19:23'	System	05 Sep 2020 23:23:45
	System	05 Sep 2020 23:23:45

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 4'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:51:33', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9a9b29e1-209e-4364-9c22-a5b8e2bda554' User entered 'None (0)'	System	07 Sep 2020 02:53:26
	System	07 Sep 2020 02:53:26

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:51:36', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9a9b29e1-209e-4364-9c22-a5b8e2bda554' User entered 'None (0)'	System	07 Sep 2020 02:53:26
	System	07 Sep 2020 02:53:26

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:51:41', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9a9b29e1-209e-4364-9c22-a5b8e2bda554' User entered 'None (0)'	System	07 Sep 2020 02:53:26
	System	07 Sep 2020 02:53:26

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:51:45', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9a9b29e1-209e-4364-9c22-a5b8e2bda554' User entered 'None (0)'	System	07 Sep 2020 02:53:26
	System	07 Sep 2020 02:53:26

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:51:49', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9a9b29e1-209e-4364-9c22-a5b8e2bda554' User entered 'None (0)'	System	07 Sep 2020 02:53:26
	System	07 Sep 2020 02:53:26

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:51:52', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9a9b29e1-209e-4364-9c22-a5b8e2bda554' User entered 'None (0)'	System	07 Sep 2020 02:53:26
	System	07 Sep 2020 02:53:26

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:53:18', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9a9b29e1-209e-4364-9c22-a5b8e2bda554' User entered 'No (N)'	System	07 Sep 2020 02:53:26
	System	07 Sep 2020 02:53:26

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-06T22:53:23', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9a9b29e1-209e-4364-9c22-a5b8e2bda554' User entered '06 Sep 2020 22:53'	System	07 Sep 2020 02:53:26
	System	07 Sep 2020 02:53:26

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 5'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:05', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3381ac2f-ae4a-41a5-8d18-f034cfe15bea' User entered 'None (0)'	System	08 Sep 2020 00:42:51
	System	08 Sep 2020 00:42:51

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:09', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3381ac2f-ae4a-41a5-8d18-f034cfe15bea' User entered 'None (0)'	System	08 Sep 2020 00:42:51
	System	08 Sep 2020 00:42:51

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:25', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3381ac2f-ae4a-41a5-8d18-f034cfe15bea' User entered 'None (0)'	System	08 Sep 2020 00:42:51
	System	08 Sep 2020 00:42:51

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:28', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3381ac2f-ae4a-41a5-8d18-f034cfe15bea' User entered 'None (0)'	System	08 Sep 2020 00:42:51
	System	08 Sep 2020 00:42:51

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:32', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3381ac2f-ae4a-41a5-8d18-f034cfe15bea' User entered 'None (0)'	System	08 Sep 2020 00:42:51
	System	08 Sep 2020 00:42:51

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:34', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3381ac2f-ae4a-41a5-8d18-f034cfe15bea' User entered 'None (0)'	System	08 Sep 2020 00:42:51
	System	08 Sep 2020 00:42:51

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3381ac2f-ae4a-41a5-8d18-f034cfe15bea'	System	08 Sep 2020 00:42:51
User entered 'No (N)'	System	08 Sep 2020 00:42:51

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-07T20:42:48', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3381ac2f-ae4a-41a5-8d18-f034cfe15bea' User entered '07 Sep 2020 20:42'	System	08 Sep 2020 00:42:51
	System	08 Sep 2020 00:42:51

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 6'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:48', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '78efa7c1-3494-4123-beb6-cc3ae5e51318' User entered 'None (0)'	System	09 Sep 2020 11:56:19
	System	09 Sep 2020 11:56:19

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:51', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '78efa7c1-3494-4123-beb6-cc3ae5e51318' User entered 'None (0)'	System	09 Sep 2020 11:56:19
	System	09 Sep 2020 11:56:19

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:54', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '78efa7c1-3494-4123-beb6-cc3ae5e51318' User entered 'None (0)'	System	09 Sep 2020 11:56:19
	System	09 Sep 2020 11:56:19

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:55:57', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '78efa7c1-3494-4123-beb6-cc3ae5e51318' User entered 'None (0)'	System	09 Sep 2020 11:56:19
	System	09 Sep 2020 11:56:19

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:56:01', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '78efa7c1-3494-4123-beb6-cc3ae5e51318' User entered 'None (0)'	System	09 Sep 2020 11:56:19
	System	09 Sep 2020 11:56:19

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:56:05', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '78efa7c1-3494-4123-beb6-cc3ae5e51318' User entered 'None (0)'	System	09 Sep 2020 11:56:19
	System	09 Sep 2020 11:56:19

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:56:12', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '78efa7c1-3494-4123-beb6-cc3ae5e51318' User entered 'No (N)'	System	09 Sep 2020 11:56:19
	System	09 Sep 2020 11:56:19

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T07:56:15', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '78efa7c1-3494-4123-beb6-cc3ae5e51318' User entered '09 Sep 2020 07:56'	System	09 Sep 2020 11:56:19
	System	09 Sep 2020 11:56:19

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 7'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:27', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'fec83326-7d0a-47a7-bdde-fa0fa9fa55ea' User entered 'None (0)'	System	09 Sep 2020 23:38:57
	System	09 Sep 2020 23:38:57

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:31', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'fec83326-7d0a-47a7-bdde-fa0fa9fa55ea' User entered 'None (0)'	System	09 Sep 2020 23:38:57
	System	09 Sep 2020 23:38:57

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:35', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'fec83326-7d0a-47a7-bdde-fa0fa9fa55ea' User entered 'None (0)'	System	09 Sep 2020 23:38:57
	System	09 Sep 2020 23:38:57

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:38', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'fec83326-7d0a-47a7-bdde-fa0fa9fa55ea' User entered 'None (0)'	System	09 Sep 2020 23:38:57
	System	09 Sep 2020 23:38:57

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:40', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'fec83326-7d0a-47a7-bdde-fa0fa9fa55ea' User entered 'None (0)'	System	09 Sep 2020 23:38:57
	System	09 Sep 2020 23:38:57

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:43', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'fec83326-7d0a-47a7-bdde-fa0fa9fa55ea' User entered 'None (0)'	System	09 Sep 2020 23:38:57
	System	09 Sep 2020 23:38:57

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:49', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'fec83326-7d0a-47a7-bdde-fa0fa9fa55ea' User entered 'No (N)'	System	09 Sep 2020 23:38:57
	System	09 Sep 2020 23:38:57

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-09-09T19:38:53', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'fec83326-7d0a-47a7-bdde-fa0fa9fa55ea' User entered '09 Sep 2020 19:38'	System	09 Sep 2020 23:38:57
	System	09 Sep 2020 23:38:57

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:11:05

US3802120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:31:42

US3802120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '10 Sep 2020'	(b) (4) Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:31:42

US3802120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:31:42

US3802120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered empty.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:31:42

US3802120

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:31:59

US3802120

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'I'	System	10 Sep 2020 20:31:59

US3802120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 15:28:30

US3802120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 09:30:12
User entered '22 Sep 2020' reason for change: Data Entry Error	Emily Dougherty (b) (4) (b) (4)	22 Sep 2020 13:09:23
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Patient contacted today' (Site from System).	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 15:28:44
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Sep 2020 15:28:30
User entered '21 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 15:28:30

US3802120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Emily Dougherty (b) (4)	22 Sep 2020 13:09:23
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Dominic Kramer (b) (4)	21 Sep 2020 15:28:30
	(b) (4)	

US3802120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'PARTICIPANT CONTACTED AND LEFT MESSAGE 3 TIMES WITHIN CONTACT WINDOW. PARTICIPANT CALLED BACK 1 DAY OUTSIDE OF WINDOW.' reason for change: Data Entry Error	Emily Dougherty (b) (4)	22 Sep 2020 13:09:23
User entered 'Participant contacted and left message three times. Patient unable to reach.'	Dominic Kramer (b) (4)	21 Sep 2020 15:28:30

US3802120

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 15:28:51

US3802120

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'I'	System	21 Sep 2020 15:28:51

US3802120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Sep 2020 14:53:29

US3802120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '25 Sep 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Sep 2020 14:53:29

US3802120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Contact Made (CONTACT MADE)'	Lalicia Roman (b) (4) (b) (4)	25 Sep 2020 14:53:29

US3802120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Lalicia Roman (b) (4)	25 Sep 2020 14:53:29

US3802120

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Sep 2020 14:53:43

US3802120

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'I'	System	25 Sep 2020 14:53:43

US3802120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:35:40

US3802120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '2 Oct 2020'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:35:40

US3802120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[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 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:35:40

US3802120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'VISIT2'	System	02 Oct 2020 13:35:40

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '2 Oct 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '09:02'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '2 Oct 2020 09:02'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '98.8' F	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Other (Other)'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '61'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'bpm'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:26:18
User entered '16' reason for change: Data Entry Error		25 Feb 2021 17:26:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '18'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'breaths/min'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '168'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '70'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '2 Oct 2020'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '10:00'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '2 Oct 2020 10:00'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '97.3' F	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Other (Other)'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Infrared'	(b) (4) Emily Carney (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '52'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'bpm'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:26:18
User entered '16' reason for change: Data Entry Error		25 Feb 2021 17:26:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '18'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'breaths/min'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '169'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '68'	Emily Carney (b) (4) (b) (4)	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	02 Oct 2020 14:13:57

US3802120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:36:09

US3802120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:36:09

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

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 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered empty.	(b) (4) Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '2 Oct 2020'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '09:29'	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '2 Oct 2020 09:29'	System	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Left Arm (LEFT ARM)'	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'ONCE'	System	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 13:36:32

US3802120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:37:06

US3802120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '2 Oct 2020'	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:37:06

US3802120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '09:25'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:37:06

US3802120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '2 Oct 2020 09:25'	System	02 Oct 2020 13:37:06

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:29:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '2 Oct 2020'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:29:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '09:20'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '2 Oct 2020 09:20'	System	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:29:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered empty.	System	02 Oct 2020 13:37:30

US3802120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	02 Oct 2020 13:36:40

US3802120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '1'	System	02 Oct 2020 13:36:40

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:04:58', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '4efedb8b-c7be-49e7-bd6f-6907cd891916' User entered 'Yes (Y)'	System	02 Oct 2020 14:05:18
	System	02 Oct 2020 14:05:18

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:04:18', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '4efedb8b-c7be-49e7-bd6f-6907cd891916' User entered '97.3'	System	02 Oct 2020 14:05:18
	System	02 Oct 2020 14:05:18

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:04:26', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '4efedb8b-c7be-49e7-bd6f-6907cd891916'	System	02 Oct 2020 14:05:18
User entered 'No (N)'	System	02 Oct 2020 14:05:18

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:05:16', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '4efedb8b-c7be-49e7-bd6f-6907cd891916'	System	02 Oct 2020 14:05:18
User entered '02 Oct 2020 10:05'	System	02 Oct 2020 14:05:18

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 09:49'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:01:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1d0620a7-295f-45bd-9a8e-b15c31b451b1' User entered 'Yes (Y)'	System	03 Oct 2020 03:02:11
	System	03 Oct 2020 03:02:11

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:01:53', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1d0620a7-295f-45bd-9a8e-b15c31b451b1' User entered '96.8'	System	03 Oct 2020 03:02:11
	System	03 Oct 2020 03:02:11

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:01:59', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1d0620a7-295f-45bd-9a8e-b15c31b451b1'	System	03 Oct 2020 03:02:11
User entered 'No (N)'	System	03 Oct 2020 03:02:11

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:02:09', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1d0620a7-295f-45bd-9a8e-b15c31b451b1' User entered '02 Oct 2020 23:02'	System	03 Oct 2020 03:02:11
	System	03 Oct 2020 03:02:11

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 13:14'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 2'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:55:40', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f4d56454-2f8a-406c-806c-4bc94cf76eab' User entered 'Yes (Y)'	System	04 Oct 2020 03:56:08
	System	04 Oct 2020 03:56:08

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:55:52', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f4d56454-2f8a-406c-806c-4bc94cf76eab' User entered '97.6'	System	04 Oct 2020 03:56:08
	System	04 Oct 2020 03:56:08

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:55:58', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f4d56454-2f8a-406c-806c-4bc94cf76eab' User entered 'No (N)'	System	04 Oct 2020 03:56:08
	System	04 Oct 2020 03:56:08

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:56:06', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f4d56454-2f8a-406c-806c-4bc94cf76eab' User entered '03 Oct 2020 23:56'	System	04 Oct 2020 03:56:08
	System	04 Oct 2020 03:56:08

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 3'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:10:50', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5339d90f-fd19-40c2-9d8f-fe5b2960dad4' User entered 'Yes (Y)'	System	05 Oct 2020 03:11:12
	System	05 Oct 2020 03:11:12

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:10:59', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5339d90f-fd19-40c2-9d8f-fe5b2960dad4' User entered '97.6'	System	05 Oct 2020 03:11:12
	System	05 Oct 2020 03:11:12

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:04', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5339d90f-fd19-40c2-9d8f-fe5b2960dad4'	System	05 Oct 2020 03:11:12
User entered 'No (N)'	System	05 Oct 2020 03:11:12

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:08', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5339d90f-fd19-40c2-9d8f-fe5b2960dad4' User entered '04 Oct 2020 23:11'	System	05 Oct 2020 03:11:12
	System	05 Oct 2020 03:11:12

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 4'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:26:48', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9d6a2b1a-a31d-477b-84fc-43be1e49fbbc' User entered 'Yes (Y)'	System	05 Oct 2020 23:27:15
	System	05 Oct 2020 23:27:15

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:26:58', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9d6a2b1a-a31d-477b-84fc-43be1e49fbbc' User entered '95.8'	System	05 Oct 2020 23:27:15
	System	05 Oct 2020 23:27:15

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:27:03', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9d6a2b1a-a31d-477b-84fc-43be1e49fbbc'	System	05 Oct 2020 23:27:15
User entered 'No (N)'	System	05 Oct 2020 23:27:15

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:27:09', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '9d6a2b1a-a31d-477b-84fc-43be1e49fbbc' User entered '05 Oct 2020 19:27'	System	05 Oct 2020 23:27:15
	System	05 Oct 2020 23:27:15

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 5'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:19:21', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'dc77fce9-4f7b-4527-b6f2-1f9891d2f5a2'	System	07 Oct 2020 01:19:45
User entered 'Yes (Y)'	System	07 Oct 2020 01:19:45

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:19:31', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'dc77fce9-4f7b-4527-b6f2-1f9891d2f5a2' User entered '97.0'	System	07 Oct 2020 01:19:45
	System	07 Oct 2020 01:19:45

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:19:38', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'dc77fce9-4f7b-4527-b6f2-1f9891d2f5a2'	System	07 Oct 2020 01:19:45
User entered 'No (N)'	System	07 Oct 2020 01:19:45

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:19:43', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'dc77fce9-4f7b-4527-b6f2-1f9891d2f5a2'	System	07 Oct 2020 01:19:45
User entered '06 Oct 2020 21:19'	System	07 Oct 2020 01:19:45

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 6'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:34:27', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8d54154f-4eee-4f1f-9e82-4cbd3caaaf52'	System	07 Oct 2020 23:34:49
User entered 'Yes (Y)'	System	07 Oct 2020 23:34:49

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:34:34', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8d54154f-4eee-4f1f-9e82-4cbd3caaaf52' User entered '97.2'	System	07 Oct 2020 23:34:49
	System	07 Oct 2020 23:34:49

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:34:39', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8d54154f-4eee-4f1f-9e82-4cbd3caaaf52'	System	07 Oct 2020 23:34:49
User entered 'No (N)'	System	07 Oct 2020 23:34:49

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:34:45', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8d54154f-4eee-4f1f-9e82-4cbd3caaaf52' User entered '07 Oct 2020 19:34'	System	07 Oct 2020 23:34:49
	System	07 Oct 2020 23:34:49

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 7'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:18', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'c814cb27-2eeb-4b4f-bb60-ec4529285cad' User entered 'Yes (Y)'	System	09 Oct 2020 02:26:36
	System	09 Oct 2020 02:26:36

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:24', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'c814cb27-2eeb-4b4f-bb60-ec4529285cad' User entered '97.2'	System	09 Oct 2020 02:26:36
	System	09 Oct 2020 02:26:36

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:28', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'c814cb27-2eeb-4b4f-bb60-ec4529285cad' User entered 'No (N)'	System	09 Oct 2020 02:26:36
	System	09 Oct 2020 02:26:36

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:34', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'c814cb27-2eeb-4b4f-bb60-ec4529285cad' User entered '08 Oct 2020 22:26'	System	09 Oct 2020 02:26:36
	System	09 Oct 2020 02:26:36

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:05:33', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '50115556-ae39-4531-a4a6-19ef9014dca2'	System	02 Oct 2020 14:05:58
User entered 'None (1)'	System	02 Oct 2020 14:05:58

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:05:40', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '50115556-ae39-4531-a4a6-19ef9014dca2' User entered 'No (N)'	System	02 Oct 2020 14:05:58
	System	02 Oct 2020 14:05:58

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:05:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '50115556-ae39-4531-a4a6-19ef9014dca2' User entered 'No (N)'	System	02 Oct 2020 14:05:58
	System	02 Oct 2020 14:05:58

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:05:49', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '50115556-ae39-4531-a4a6-19ef9014dca2'	System	02 Oct 2020 14:05:58
User entered 'None (1)'	System	02 Oct 2020 14:05:58

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:05:55', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '50115556-ae39-4531-a4a6-19ef9014dca2' User entered '02 Oct 2020 10:05'	System	02 Oct 2020 14:05:58
	System	02 Oct 2020 14:05:58

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 09:49'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:02:34', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd78032c5-401b-4442-bad1-49fbd126c5dc' User entered 'None (1)'	System	03 Oct 2020 03:06:31
	System	03 Oct 2020 03:06:31

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:05:19', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd78032c5-401b-4442-bad1-49fbd126c5dc' User entered 'No (N)'	System	03 Oct 2020 03:06:31
	System	03 Oct 2020 03:06:31

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:05:55', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd78032c5-401b-4442-bad1-49fbd126c5dc' User entered 'No (N)'	System	03 Oct 2020 03:06:31
	System	03 Oct 2020 03:06:31

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:06:06', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd78032c5-401b-4442-bad1-49fbd126c5dc' User entered 'None (1)'	System	03 Oct 2020 03:06:31
	System	03 Oct 2020 03:06:31

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:06:29', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd78032c5-401b-4442-bad1-49fbd126c5dc' User entered '02 Oct 2020 23:06'	System	03 Oct 2020 03:06:31
	System	03 Oct 2020 03:06:31

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 13:14'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 2'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:03', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1f26e7f6-1f90-4ad5-a3db-64a8e32777d2'	System	04 Oct 2020 03:58:21
User entered 'None (1)'	System	04 Oct 2020 03:58:21

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:07', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1f26e7f6-1f90-4ad5-a3db-64a8e32777d2'	System	04 Oct 2020 03:58:21
User entered 'No (N)'	System	04 Oct 2020 03:58:21

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:10', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1f26e7f6-1f90-4ad5-a3db-64a8e32777d2'	System	04 Oct 2020 03:58:21
User entered 'No (N)'	System	04 Oct 2020 03:58:21

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:15', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1f26e7f6-1f90-4ad5-a3db-64a8e32777d2'	System	04 Oct 2020 03:58:21
User entered 'None (1)'	System	04 Oct 2020 03:58:21

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:18', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '1f26e7f6-1f90-4ad5-a3db-64a8e32777d2'	System	04 Oct 2020 03:58:21
User entered '03 Oct 2020 23:58'	System	04 Oct 2020 03:58:21

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 3'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:18', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '13133059-5518-48f6-8ba9-02ad2bbccb22'	System	05 Oct 2020 03:11:36
User entered 'None (1)'	System	05 Oct 2020 03:11:36

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:23', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '13133059-5518-48f6-8ba9-02ad2bbccb22'	System	05 Oct 2020 03:11:36
User entered 'No (N)'	System	05 Oct 2020 03:11:36

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:27', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '13133059-5518-48f6-8ba9-02ad2bbccb22'	System	05 Oct 2020 03:11:36
User entered 'No (N)'	System	05 Oct 2020 03:11:36

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:30', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '13133059-5518-48f6-8ba9-02ad2bbccb22'	System	05 Oct 2020 03:11:36
User entered 'None (1)'	System	05 Oct 2020 03:11:36

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:34', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '13133059-5518-48f6-8ba9-02ad2bbccb22'	System	05 Oct 2020 03:11:36
User entered '04 Oct 2020 23:11'	System	05 Oct 2020 03:11:36

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 4'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:27:19', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b755dd50-be50-42c0-aa2a-ad16bb9d426e' User entered 'None (1)'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:27:23', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b755dd50-be50-42c0-aa2a-ad16bb9d426e' User entered 'No (N)'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:27:46', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b755dd50-be50-42c0-aa2a-ad16bb9d426e' User entered 'No (N)'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:27:52', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b755dd50-be50-42c0-aa2a-ad16bb9d426e' User entered 'None (1)'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:27:55', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b755dd50-be50-42c0-aa2a-ad16bb9d426e' User entered '05 Oct 2020 19:27'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 5'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:19:49', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6293835-f7de-42d9-98ff-de253b31824a'	System	07 Oct 2020 01:20:10
User entered 'None (1)'	System	07 Oct 2020 01:20:10

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:19:53', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6293835-f7de-42d9-98ff-de253b31824a' User entered 'No (N)'	System	07 Oct 2020 01:20:10
	System	07 Oct 2020 01:20:10

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:19:57', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6293835-f7de-42d9-98ff-de253b31824a' User entered 'No (N)'	System	07 Oct 2020 01:20:10
	System	07 Oct 2020 01:20:10

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:03', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6293835-f7de-42d9-98ff-de253b31824a'	System	07 Oct 2020 01:20:10
User entered 'None (1)'	System	07 Oct 2020 01:20:10

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:08', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e6293835-f7de-42d9-98ff-de253b31824a' User entered '06 Oct 2020 21:20'	System	07 Oct 2020 01:20:10
	System	07 Oct 2020 01:20:10

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 6'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:34:53', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e3931584-9259-4f0e-ba98-33c5978a0949'	System	07 Oct 2020 23:35:12
User entered 'None (1)'	System	07 Oct 2020 23:35:12

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:34:57', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e3931584-9259-4f0e-ba98-33c5978a0949' User entered 'No (N)'	System	07 Oct 2020 23:35:12
	System	07 Oct 2020 23:35:12

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e3931584-9259-4f0e-ba98-33c5978a0949' User entered 'No (N)'	System	07 Oct 2020 23:35:12
	System	07 Oct 2020 23:35:12

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:04', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e3931584-9259-4f0e-ba98-33c5978a0949'	System	07 Oct 2020 23:35:12
User entered 'None (1)'	System	07 Oct 2020 23:35:12

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:08', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e3931584-9259-4f0e-ba98-33c5978a0949' User entered '07 Oct 2020 19:35'	System	07 Oct 2020 23:35:12
	System	07 Oct 2020 23:35:12

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 7'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:40', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'ebbee8f9-6685-44f8-ad0d-d0a9be0490ba' User entered 'None (1)'	System	09 Oct 2020 02:26:56
	System	09 Oct 2020 02:26:56

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'ebbee8f9-6685-44f8-ad0d-d0a9be0490ba' User entered 'No (N)'	System	09 Oct 2020 02:26:56
	System	09 Oct 2020 02:26:56

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:47', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'ebbee8f9-6685-44f8-ad0d-d0a9be0490ba' User entered 'No (N)'	System	09 Oct 2020 02:26:56
	System	09 Oct 2020 02:26:56

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:50', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'ebbee8f9-6685-44f8-ad0d-d0a9be0490ba' User entered 'None (1)'	System	09 Oct 2020 02:26:56
	System	09 Oct 2020 02:26:56

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:26:54', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'ebbee8f9-6685-44f8-ad0d-d0a9be0490ba' User entered '08 Oct 2020 22:26'	System	09 Oct 2020 02:26:56
	System	09 Oct 2020 02:26:56

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:06:01', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5997606a-e6af-4e6a-b4e0-3be8d9ff0d6a' User entered 'None (0)'	System	02 Oct 2020 14:06:26
	System	02 Oct 2020 14:06:26

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:06:03', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5997606a-e6af-4e6a-b4e0-3be8d9ff0d6a' User entered 'None (0)'	System	02 Oct 2020 14:06:26
	System	02 Oct 2020 14:06:26

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:06:06', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5997606a-e6af-4e6a-b4e0-3be8d9ff0d6a' User entered 'None (0)'	System	02 Oct 2020 14:06:26
	System	02 Oct 2020 14:06:26

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:06:09', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5997606a-e6af-4e6a-b4e0-3be8d9ff0d6a' User entered 'None (0)'	System	02 Oct 2020 14:06:26
	System	02 Oct 2020 14:06:26

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:06:12', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5997606a-e6af-4e6a-b4e0-3be8d9ff0d6a' User entered 'None (0)'	System	02 Oct 2020 14:06:26
	System	02 Oct 2020 14:06:26

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:06:15', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5997606a-e6af-4e6a-b4e0-3be8d9ff0d6a' User entered 'None (0)'	System	02 Oct 2020 14:06:26
	System	02 Oct 2020 14:06:26

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:06:20', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5997606a-e6af-4e6a-b4e0-3be8d9ff0d6a' User entered 'No (N)'	System	02 Oct 2020 14:06:26
	System	02 Oct 2020 14:06:26

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T10:06:23', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '5997606a-e6af-4e6a-b4e0-3be8d9ff0d6a' User entered '02 Oct 2020 10:06'	System	02 Oct 2020 14:06:26
	System	02 Oct 2020 14:06:26

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 09:49'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:06:37', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e8336f86-0d36-4424-a856-991650d73a45' User entered 'None (0)'	System	03 Oct 2020 03:07:15
	System	03 Oct 2020 03:07:15

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:06:41', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e8336f86-0d36-4424-a856-991650d73a45' User entered 'None (0)'	System	03 Oct 2020 03:07:15
	System	03 Oct 2020 03:07:15

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:06:44', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e8336f86-0d36-4424-a856-991650d73a45' User entered 'None (0)'	System	03 Oct 2020 03:07:15
	System	03 Oct 2020 03:07:15

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:06:48', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e8336f86-0d36-4424-a856-991650d73a45' User entered 'None (0)'	System	03 Oct 2020 03:07:15
	System	03 Oct 2020 03:07:15

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:06:52', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e8336f86-0d36-4424-a856-991650d73a45' User entered 'None (0)'	System	03 Oct 2020 03:07:15
	System	03 Oct 2020 03:07:15

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:06:55', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e8336f86-0d36-4424-a856-991650d73a45' User entered 'None (0)'	System	03 Oct 2020 03:07:15
	System	03 Oct 2020 03:07:15

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:07:02', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e8336f86-0d36-4424-a856-991650d73a45'	System	03 Oct 2020 03:07:15
User entered 'No (N)'	System	03 Oct 2020 03:07:15

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-02T23:07:08', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'e8336f86-0d36-4424-a856-991650d73a45' User entered '02 Oct 2020 23:07'	System	03 Oct 2020 03:07:15
	System	03 Oct 2020 03:07:15

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '02 Oct 2020 13:14'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 2'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:24', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd376126e-9e65-454e-aeb6-abd7ef2af489' User entered 'None (0)'	System	04 Oct 2020 03:58:53
	System	04 Oct 2020 03:58:53

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:27', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd376126e-9e65-454e-aeb6-abd7ef2af489' User entered 'None (0)'	System	04 Oct 2020 03:58:53
	System	04 Oct 2020 03:58:53

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:30', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd376126e-9e65-454e-aeb6-abd7ef2af489' User entered 'None (0)'	System	04 Oct 2020 03:58:53
	System	04 Oct 2020 03:58:53

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:32', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd376126e-9e65-454e-aeb6-abd7ef2af489' User entered 'None (0)'	System	04 Oct 2020 03:58:53
	System	04 Oct 2020 03:58:53

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:35', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd376126e-9e65-454e-aeb6-abd7ef2af489' User entered 'None (0)'	System	04 Oct 2020 03:58:53
	System	04 Oct 2020 03:58:53

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:37', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd376126e-9e65-454e-aeb6-abd7ef2af489' User entered 'None (0)'	System	04 Oct 2020 03:58:53
	System	04 Oct 2020 03:58:53

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:46', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd376126e-9e65-454e-aeb6-abd7ef2af489' User entered 'No (N)'	System	04 Oct 2020 03:58:53
	System	04 Oct 2020 03:58:53

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-03T23:58:51', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'd376126e-9e65-454e-aeb6-abd7ef2af489' User entered '03 Oct 2020 23:58'	System	04 Oct 2020 03:58:53
	System	04 Oct 2020 03:58:53

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 3'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:40', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '95918bb0-0b74-4930-a29b-13c02e069ec3' User entered 'None (0)'	System	05 Oct 2020 03:12:07
	System	05 Oct 2020 03:12:07

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:43', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '95918bb0-0b74-4930-a29b-13c02e069ec3' User entered 'None (0)'	System	05 Oct 2020 03:12:07
	System	05 Oct 2020 03:12:07

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:46', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '95918bb0-0b74-4930-a29b-13c02e069ec3' User entered 'None (0)'	System	05 Oct 2020 03:12:07
	System	05 Oct 2020 03:12:07

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:49', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '95918bb0-0b74-4930-a29b-13c02e069ec3' User entered 'None (0)'	System	05 Oct 2020 03:12:07
	System	05 Oct 2020 03:12:07

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:52', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '95918bb0-0b74-4930-a29b-13c02e069ec3' User entered 'None (0)'	System	05 Oct 2020 03:12:07
	System	05 Oct 2020 03:12:07

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:11:54', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '95918bb0-0b74-4930-a29b-13c02e069ec3' User entered 'None (0)'	System	05 Oct 2020 03:12:07
	System	05 Oct 2020 03:12:07

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:12:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '95918bb0-0b74-4930-a29b-13c02e069ec3' User entered 'No (N)'	System	05 Oct 2020 03:12:07
	System	05 Oct 2020 03:12:07

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-04T23:12:03', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '95918bb0-0b74-4930-a29b-13c02e069ec3' User entered '04 Oct 2020 23:12'	System	05 Oct 2020 03:12:07
	System	05 Oct 2020 03:12:07

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 4'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:28:07', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b307413f-fd01-4626-b938-6b5a7af954a8' User entered 'None (0)'	System	05 Oct 2020 23:28:40
	System	05 Oct 2020 23:28:40

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:28:10', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b307413f-fd01-4626-b938-6b5a7af954a8' User entered 'None (0)'	System	05 Oct 2020 23:28:40
	System	05 Oct 2020 23:28:40

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:28:13', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b307413f-fd01-4626-b938-6b5a7af954a8' User entered 'None (0)'	System	05 Oct 2020 23:28:40
	System	05 Oct 2020 23:28:40

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:28:16', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b307413f-fd01-4626-b938-6b5a7af954a8' User entered 'None (0)'	System	05 Oct 2020 23:28:40
	System	05 Oct 2020 23:28:40

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:28:19', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b307413f-fd01-4626-b938-6b5a7af954a8' User entered 'None (0)'	System	05 Oct 2020 23:28:40
	System	05 Oct 2020 23:28:40

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:28:22', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b307413f-fd01-4626-b938-6b5a7af954a8' User entered 'None (0)'	System	05 Oct 2020 23:28:40
	System	05 Oct 2020 23:28:40

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:28:33', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b307413f-fd01-4626-b938-6b5a7af954a8' User entered 'No (N)'	System	05 Oct 2020 23:28:40
	System	05 Oct 2020 23:28:40

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-05T19:28:37', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'b307413f-fd01-4626-b938-6b5a7af954a8' User entered '05 Oct 2020 19:28'	System	05 Oct 2020 23:28:40
	System	05 Oct 2020 23:28:40

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 5'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:13', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '27364263-a78b-4f5f-ba41-4889724fa22c' User entered 'None (0)'	System	07 Oct 2020 01:21:13
	System	07 Oct 2020 01:21:13

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:15', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '27364263-a78b-4f5f-ba41-4889724fa22c' User entered 'None (0)'	System	07 Oct 2020 01:21:13
	System	07 Oct 2020 01:21:13

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:18', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '27364263-a78b-4f5f-ba41-4889724fa22c' User entered 'None (0)'	System	07 Oct 2020 01:21:13
	System	07 Oct 2020 01:21:13

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:20', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '27364263-a78b-4f5f-ba41-4889724fa22c' User entered 'None (0)'	System	07 Oct 2020 01:21:13
	System	07 Oct 2020 01:21:13

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:23', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '27364263-a78b-4f5f-ba41-4889724fa22c' User entered 'None (0)'	System	07 Oct 2020 01:21:13
	System	07 Oct 2020 01:21:13

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:25', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '27364263-a78b-4f5f-ba41-4889724fa22c' User entered 'None (0)'	System	07 Oct 2020 01:21:13
	System	07 Oct 2020 01:21:13

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:31', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '27364263-a78b-4f5f-ba41-4889724fa22c' User entered 'No (N)'	System	07 Oct 2020 01:21:13
	System	07 Oct 2020 01:21:13

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-06T21:20:34', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '27364263-a78b-4f5f-ba41-4889724fa22c' User entered '06 Oct 2020 21:20'	System	07 Oct 2020 01:21:13
	System	07 Oct 2020 01:21:13

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 6'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:13', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '086e1b68-2e6c-4901-92ae-0ff8ca66163b' User entered 'None (0)'	System	07 Oct 2020 23:35:37
	System	07 Oct 2020 23:35:37

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:16', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '086e1b68-2e6c-4901-92ae-0ff8ca66163b' User entered 'None (0)'	System	07 Oct 2020 23:35:37
	System	07 Oct 2020 23:35:37

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:18', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '086e1b68-2e6c-4901-92ae-0ff8ca66163b' User entered 'None (0)'	System	07 Oct 2020 23:35:37
	System	07 Oct 2020 23:35:37

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:21', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '086e1b68-2e6c-4901-92ae-0ff8ca66163b' User entered 'None (0)'	System	07 Oct 2020 23:35:37
	System	07 Oct 2020 23:35:37

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:24', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '086e1b68-2e6c-4901-92ae-0ff8ca66163b' User entered 'None (0)'	System	07 Oct 2020 23:35:37
	System	07 Oct 2020 23:35:37

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:26', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '086e1b68-2e6c-4901-92ae-0ff8ca66163b' User entered 'None (0)'	System	07 Oct 2020 23:35:37
	System	07 Oct 2020 23:35:37

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:33', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '086e1b68-2e6c-4901-92ae-0ff8ca66163b' User entered 'No (N)'	System	07 Oct 2020 23:35:37
	System	07 Oct 2020 23:35:37

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-07T19:35:36', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '086e1b68-2e6c-4901-92ae-0ff8ca66163b' User entered '07 Oct 2020 19:35'	System	07 Oct 2020 23:35:37
	System	07 Oct 2020 23:35:37

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
Data entry locked.	System	02 Oct 2020 13:36:32
User entered 'Day 7'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:27:01', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3b46cf68-6f69-476f-a4c8-8858df5e8f0b' User entered 'None (0)'	System	09 Oct 2020 02:27:30
	System	09 Oct 2020 02:27:30

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:27:04', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3b46cf68-6f69-476f-a4c8-8858df5e8f0b' User entered 'None (0)'	System	09 Oct 2020 02:27:30
	System	09 Oct 2020 02:27:30

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:27:06', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3b46cf68-6f69-476f-a4c8-8858df5e8f0b' User entered 'None (0)'	System	09 Oct 2020 02:27:30
	System	09 Oct 2020 02:27:30

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:27:10', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3b46cf68-6f69-476f-a4c8-8858df5e8f0b' User entered 'None (0)'	System	09 Oct 2020 02:27:30
	System	09 Oct 2020 02:27:30

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:27:12', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3b46cf68-6f69-476f-a4c8-8858df5e8f0b' User entered 'None (0)'	System	09 Oct 2020 02:27:30
	System	09 Oct 2020 02:27:30

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:27:16', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3b46cf68-6f69-476f-a4c8-8858df5e8f0b' User entered 'None (0)'	System	09 Oct 2020 02:27:30
	System	09 Oct 2020 02:27:30

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

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)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:27:24', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3b46cf68-6f69-476f-a4c8-8858df5e8f0b' User entered 'No (N)'	System	09 Oct 2020 02:27:30
	System	09 Oct 2020 02:27:30

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (964E9077-00AD-42AE-892F-09076BAECF83)', Time: '2020-10-08T22:27:28', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '3b46cf68-6f69-476f-a4c8-8858df5e8f0b' User entered '08 Oct 2020 22:27'	System	09 Oct 2020 02:27:30
	System	09 Oct 2020 02:27:30

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 13:36:32

US3802120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:29:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:17:24
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 13:36:32

US3802120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Emily Dougherty (b) (4) (b) (4)	12 Oct 2020 20:46:04

US3802120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '12 Oct 2020'	Emily Dougherty (b) (4) (b) (4)	12 Oct 2020 20:46:04

US3802120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Contact Made (CONTACT MADE)'	Emily Dougherty (b) (4) (b) (4)	12 Oct 2020 20:46:04

US3802120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Emily Dougherty (b) (4) (b) (4)	12 Oct 2020 20:46:04

US3802120

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Dougherty (b) (4)	12 Oct 2020 20:46:07

US3802120

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'I'	System	12 Oct 2020 20:46:07

US3802120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 17:16:53

US3802120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '18 Oct 2020'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 17:16:53

US3802120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 17:16:53

US3802120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'attempted three times'	Jennifer Nagg (b) (4)	19 Oct 2020 17:16:53

US3802120

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 17:16:58

US3802120

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'I'	System	19 Oct 2020 17:16:58

US3802120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	23 Oct 2020 19:42:28

US3802120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '23 Oct 2020'	(b) (4) Dominic Kramer (b) (4)	23 Oct 2020 19:42:28

US3802120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Contact Made (CONTACT MADE)'	Dominic Kramer (b) (4) (b) (4)	23 Oct 2020 19:42:28

US3802120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Dominic Kramer (b) (4) (b) (4)	23 Oct 2020 19:42:28

US3802120

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	23 Oct 2020 19:42:32

US3802120

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'I'	System	23 Oct 2020 19:42:32

US3802120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:17:37

US3802120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '3 Nov 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:17:37

US3802120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[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 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Clinic (Clinic)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:17:37

US3802120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'VISIT3'	System	03 Nov 2020 14:17:37

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '3 Nov 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '08:54'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '3 Nov 2020 08:54'	System	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '97.4' F	Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Infrared'	Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '70'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'bpm'	System	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '18'	Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'breaths/min'	System	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '156'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '60'	Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'mmHg'	System	03 Nov 2020 14:18:03

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57

US3802120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57

US3802120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:08

US3802120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:08

US3802120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:17

US3802120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '3 Nov 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:17

US3802120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '09:10'	Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:17

US3802120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '3 Nov 2020 09:10'	System	03 Nov 2020 14:18:17

US3802120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Nov 2020 14:18:21

US3802120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered '1'	System	03 Nov 2020 14:18:21

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 64'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Have you been exposed to someone with 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 71'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Have you been exposed to someone with 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered 'Day 78'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Have you been exposed to someone with 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Please 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 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 14:11:05

US3802120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:06:40
Data entry locked.	System	03 Sep 2020 14:11:05
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 14:11:05

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-03-23T16:01:02-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f1ee8dee-31b1-4dad-8d36-5ec197f82239'	System	23 Mar 2021 20:01:46
User entered 'No (N)'	System	23 Mar 2021 20:01:46

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Have you been exposed to someone with 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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-03-23T16:01:16-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f1ee8dee-31b1-4dad-8d36-5ec197f82239'	System	23 Mar 2021 20:01:46
User entered 'No (N)'	System	23 Mar 2021 20:01:46

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-03-23T16:01:41-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'f1ee8dee-31b1-4dad-8d36-5ec197f82239' User entered '23 Mar 2021 16:01:41'	System	23 Mar 2021 20:01:46
	System	23 Mar 2021 20:01:46

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-03-27T08:52:56-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '19a44d63-5f9c-4a90-85a7-89c7166b7f85'	System	31 Mar 2021 16:56:41
User entered 'No (N)'	System	31 Mar 2021 16:56:41

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Have you been exposed to someone with 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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-03-27T08:53:09-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '19a44d63-5f9c-4a90-85a7-89c7166b7f85'	System	31 Mar 2021 16:56:41
User entered 'No (N)'	System	31 Mar 2021 16:56:41

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-03-27T08:53:30-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '19a44d63-5f9c-4a90-85a7-89c7166b7f85'	System	31 Mar 2021 16:56:41
User entered '27 Mar 2021 08:53:30'	System	31 Mar 2021 16:56:41

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-05T08:57:37-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '60e37ba5-3a57-442f-bccf-7c7280ecfee3' User entered 'No (N)'	System	05 Apr 2021 12:58:05
	System	05 Apr 2021 12:58:05

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Have you been exposed to someone with 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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-05T08:57:45-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '60e37ba5-3a57-442f-bccf-7c7280ecfee3' User entered 'No (N)'	System	05 Apr 2021 12:58:05
	System	05 Apr 2021 12:58:05

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-05T08:58:00-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '60e37ba5-3a57-442f-bccf-7c7280ecfee3'	System	05 Apr 2021 12:58:05
User entered '05 Apr 2021 08:58:00'	System	05 Apr 2021 12:58:05

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-10T18:35:29-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8c3fa9e6-b8a2-40ca-8536-b456060722b3' User entered 'No (N)'	System	10 Apr 2021 22:35:53

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Have you been exposed to someone with 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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-10T18:35:43-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8c3fa9e6-b8a2-40ca-8536-b456060722b3' User entered 'No (N)'	System	10 Apr 2021 22:35:53

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-10T18:35:50-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '8c3fa9e6-b8a2-40ca-8536-b456060722b3' User entered '10 Apr 2021 18:35:50'	System	10 Apr 2021 22:35:53
	System	10 Apr 2021 22:35:53

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-17T22:39:07-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'a9d62820-6f19-438b-bbb9-140de3b7152f' User entered 'No (N)'	System	18 Apr 2021 02:39:27
	System	18 Apr 2021 02:39:27

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

Have you been exposed to someone with 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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-17T22:39:16-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'a9d62820-6f19-438b-bbb9-140de3b7152f'	System	18 Apr 2021 02:39:27
User entered 'No (N)'	System	18 Apr 2021 02:39:27

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-17T22:39:24-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'a9d62820-6f19-438b-bbb9-140de3b7152f' User entered '17 Apr 2021 22:39:24'	System	18 Apr 2021 02:39:27
	System	18 Apr 2021 02:39:27

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-24T12:19:44-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '89e2e256-2cc3-4d8f-98a7-ae4969432b79' User entered 'No (N)'	System	24 Apr 2021 16:20:02
	System	24 Apr 2021 16:20:02

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Have you been exposed to someone with 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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-24T12:19:51-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '89e2e256-2cc3-4d8f-98a7-ae4969432b79' User entered 'No (N)'	System	24 Apr 2021 16:20:02
	System	24 Apr 2021 16:20:02

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-04-24T12:19:58-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: '89e2e256-2cc3-4d8f-98a7-ae4969432b79' User entered '24 Apr 2021 12:19:58'	System	24 Apr 2021 16:20:02
	System	24 Apr 2021 16:20:02

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-05-02T23:07:26-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'ed68b92d-2913-452d-a3d3-7fd30db9f73a'	System	03 May 2021 03:07:48
User entered 'No (N)'	System	03 May 2021 03:07:48

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Have you been exposed to someone with 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 (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-05-02T23:07:34-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'ed68b92d-2913-452d-a3d3-7fd30db9f73a'	System	03 May 2021 03:07:48
User entered 'No (N)'	System	03 May 2021 03:07:48

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-05-02T23:07:46-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'ed68b92d-2913-452d-a3d3-7fd30db9f73a'	System	03 May 2021 03:07:48
User entered '02 May 2021 23:07:46'	System	03 May 2021 03:07:48

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:06:40

US3802120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:29:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:06:40
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:06:40

US3802120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:29:33

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 19:16:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-03-23T16:02:06-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'bd75d3fb-f56b-4f56-84c0-e4bbd30f797e'	System	23 Mar 2021 20:02:18
User entered 'No (N)'	System	23 Mar 2021 20:02:18

US3802120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:29:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:16:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D22D58FD-FF54-48AD-800C-3D09A215F83D)', Time: '2021-03-23T16:02:14-04:00', User OID: 'PatientReportedOutcome (US3802120)', ODM File OID: 'bd75d3fb-f56b-4f56-84c0-e4bbd30f797e'	System	23 Mar 2021 20:02:18
User entered '23 Mar 2021 16:02:14'	System	23 Mar 2021 20:02:18

US3802120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	24 Nov 2020 19:59:06

US3802120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '24 Nov 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	24 Nov 2020 19:59:06

US3802120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Contact Made (CONTACT MADE)'	Emily Carney (b) (4) (b) (4)	24 Nov 2020 19:59:06

US3802120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	24 Nov 2020 19:59:06

US3802120

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	24 Nov 2020 19:59:11

US3802120

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:01:57
User entered 'I'	System	24 Nov 2020 19:59:11

US3802120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Jan 2021 14:10:30

US3802120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '29 Dec 2020'	(b) (4) Lalicia Roman (b) (4)	05 Jan 2021 14:10:30

US3802120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lalicia Roman (b) (4)	05 Jan 2021 14:10:30

US3802120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Lalicia Roman (b) (4) (b) (4)	05 Jan 2021 14:10:30

US3802120

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Jan 2021 14:10:34

US3802120

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered 'I'	System	05 Jan 2021 14:10:34

US3802120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:30:44
User entered 'Yes (Y)'	Emily Dougherty (b) (4) (b) (4)	01 Feb 2021 19:30:29

US3802120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	01 Feb 2021 19:30:34
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	01 Feb 2021 19:30:34
User entered '01 Feb 2021' reason for change: Data Entry Error	Emily Dougherty (b) (4)	01 Feb 2021 19:30:34
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	01 Feb 2021 19:30:29
User entered '01 Jan 2021'	Emily Dougherty (b) (4)	01 Feb 2021 19:30:29

US3802120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:30:44
User entered 'Contact Made (CONTACT MADE)'	Emily Dougherty (b) (4) (b) (4)	01 Feb 2021 19:30:29

US3802120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered empty.	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Feb 2021 19:30:29

US3802120

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:30:44
User entered 'Yes (Y)'	Emily Dougherty (b) (4) (b) (4)	01 Feb 2021 19:30:38

US3802120

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered '1'	System	01 Feb 2021 19:30:38

US3802120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Mar 2021 15:20:35

US3802120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered '2 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Mar 2021 15:20:35

US3802120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Mar 2021 15:20:35

US3802120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	03 Mar 2021 16:32:52
User entered empty.	Emily Carney (b) (4) (b) (4)	02 Mar 2021 15:20:35

US3802120

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	02 Mar 2021 15:20:25

US3802120

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered 'I'	System	02 Mar 2021 15:20:25

US3802120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:41:25

US3802120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '23 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:41:25

US3802120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Clinic (Clinic)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:41:25

US3802120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered 'VISIT4'	System	23 Mar 2021 18:41:25

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered '23 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered '14:11'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered '23 Mar 2021 14:11'	System	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	31 Mar 2021 19:47:57
User entered '97.8' F	Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered '63'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered 'bpm'	System	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	31 Mar 2021 19:47:57
User entered '20'	Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered 'breaths/min'	System	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	31 Mar 2021 19:47:57
User entered '142'	Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered 'mmHg'	System	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered '66'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered 'mmHg'	System	31 Mar 2021 14:11:19

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18

US3802120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18

US3802120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:41:32

US3802120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:41:32

US3802120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:42:18

US3802120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '23 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:42:18

US3802120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '14:18'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:42:18

US3802120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered '23 Mar 2021 14:18'	System	23 Mar 2021 18:42:18

US3802120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:42:24

US3802120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:20:18
User entered '1'	System	23 Mar 2021 18:42:24

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:29:33

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:41
DataPoint Verified.		22 Feb 2021 06:49:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '15 Jan 2021'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:16:07

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:29:33

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:41
DataPoint Verified.		22 Feb 2021 06:49:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '12:13'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:16:07

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:29:33

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:41
User entered '15 Jan 2021 12:13'	System	15 Jan 2021 18:16:07

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:29:33

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:41
DataPoint Verified.		22 Feb 2021 06:49:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:16:07

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:29:33

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:41
DataPoint Verified.		22 Feb 2021 06:49:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:16:07

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 1 (Day 1)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:36:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '15 Jan 2021'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:36:28
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:36:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:36:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97.6' F	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:36:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:37:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:37:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:37:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:38:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:38:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:38:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:38:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:38:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	Jamie Fries (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:38:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:39:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:39:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Moderate (Moderate)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:39:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:39:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:39:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:39:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:20:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 2 (Day 2)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:31:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '16 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:31:38
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:31:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '96'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	20 Jan 2021 13:16:54

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:31:43
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '98.4' F	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:31:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:31:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:01
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:16:54
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:16:54
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:16:54
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:11
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:16:54
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:14
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:16:54
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:32:42
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 06:32:40
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:32:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	Emily Carney (b) (4)	20 Jan 2021 13:16:54

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:19
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:25
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:28
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:32:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:16:54

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 3 (Day 3)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:03
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '17 Jan 2021'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:12:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	Emily Carney (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97.6' F	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:19
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:27
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:38
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:43
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:12:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:20:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:05
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:11
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:44
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:18:01
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:47
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 06:21:54
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:18:01

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 4 (Day 4)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:08:31
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '18 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:08:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:08:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '98'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	20 Jan 2021 13:19:02

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:08:39
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97.6' F	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:08:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:08:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Moderate (Moderate)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 07:09:43
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	Emily Carney (b) (4)	20 Jan 2021 13:19:02

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:09:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:09:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:11
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:08
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:07
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:19:02
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:05
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:01
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:19:02
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:09:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:09:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Emily Carney (b) (4) (b) (4)	20 Jan 2021 13:19:02

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:09:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	20 Jan 2021 13:19:02
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 5 (Day 5)'	(b) (4) Dominic Kramer (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '19 Jan 2021'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:54
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97.3' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:10:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:14
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:20
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:22
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:11:25
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:12:19
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:12:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:12:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:12:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:12:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:12:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 18:52:39

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 6 (Day 6)'	(b) (4) Dominic Kramer (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '20 Jan 2021'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '96'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	22 Jan 2021 19:14:36

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Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97.6' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:47
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:14:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:15:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 07:15:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	Dominic Kramer (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 07:15:31
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	Dominic Kramer (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:15:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Form: Symptom Log (6)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:15:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:15:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (6)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:15:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:15:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:15:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:14:36

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Form: Symptom Log (7)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 7 (Day 7)'	(b) (4) Dominic Kramer (b) (4)	22 Jan 2021 19:15:32

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Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:19:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '21 Jan 2021'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:19:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:20:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '98'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	22 Jan 2021 19:15:32

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:20:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '98.1' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:20:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Apr 2021 16:04:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:20:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

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Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:19
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:23
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:25
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:33
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:31
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:24:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	22 Jan 2021 19:15:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 9 (Day 9)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

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Folder: Covid-19 Assessment 15 Jan 2021

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:25:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '23 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		22 Feb 2021 07:25:58
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

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Form: Symptom Log (8)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:11:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	26 Jan 2021 14:21:54

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:11:43
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '98.0' F	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 04:12:20
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 04:12:13
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 04:12:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	Emily Carney (b) (4)	26 Jan 2021 14:21:54

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:12:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

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Folder: Covid-19 Assessment 15 Jan 2021

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:12:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:21:54
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:12:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:12:54
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:12:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:12:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:21:54
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:13:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:21:54
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:13:42
DataPoint Un-verified.		04 Mar 2021 04:13:34
DataPoint Verified.		04 Mar 2021 04:13:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:13:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:13:39
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:21:54
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:13:44
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:13:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:13:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:14:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:14:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:21:54

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 10 (Day 10)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:15:20
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '24 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:15:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:25:59
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:15:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '98'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	26 Jan 2021 14:25:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:15:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97.6' F	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:25:59
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:15:54
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:15:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:16:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:18:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:19:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:19:22
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:19:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:19:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:19:39
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:19:54
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:19:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:20:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:20:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:20:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:20:31
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:25:59
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:20:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:25:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 11 (Day 11)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:20:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '25 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:21:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:21:07
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	26 Jan 2021 14:31:56

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:21:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97.3' F	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:21:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:29:34
DataPoint Un-verified.		04 Mar 2021 04:28:00
DataPoint Verified.		04 Mar 2021 04:27:58
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:29:38
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:29:44
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:29:47
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:29:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:29:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:29:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:30:11
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:30:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4)	
	Emily Carney (b) (4)	26 Jan 2021 14:31:56
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:30:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:30:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:30:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:30:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:30:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:30:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Carney (b) (4) (b) (4)	26 Jan 2021 14:31:56

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Day 8 (Day 8)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '22 Jan 2021'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:14
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '97.3' F	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:25
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:27
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:31
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:43
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:36:56
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Form: Symptom Log (11)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:37:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:37:03
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:37:16
DataPoint Un-verified.		04 Mar 2021 04:37:11
DataPoint Verified.		04 Mar 2021 04:37:05
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:37:22
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:37:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:37:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:37:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	26 Jan 2021 20:42:59

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'Day 13 (Day 13)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:38:26
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '27 Jan 2021'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:13
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '99'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	02 Feb 2021 16:17:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:17
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '98.0' F	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:22
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:28
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:32
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:41
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:44
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:47
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Form: Symptom Log (12)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:50
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:54
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:39:57
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:07
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:13
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:16
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:18
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:17:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'Day 14 (Day 14)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:58
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '28 Jan 2021'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:01
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '98'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:15
DataPoint Un-verified.		04 Mar 2021 04:42:12
DataPoint Verified.		04 Mar 2021 04:42:10
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '98.0' F	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:18
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:21
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:23
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:27
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:41
DataPoint Un-verified.		04 Mar 2021 04:42:32
DataPoint Verified.		04 Mar 2021 04:42:29
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:35
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:43
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:47
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:49
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:52
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:55
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:42:57
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:43:00
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:43:03
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:43:06
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:43:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:18:27

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'Day 12 (Day 12)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:46
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '26 Jan 2021'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:48
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:51
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '99'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
User entered '%'	System	02 Feb 2021 16:21:17

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:54
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '97.0' F	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:40:57
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:00
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:07
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:09
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:14
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:18
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:21
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:23
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:27
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:30
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:35
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:40
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:43
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:45
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:29:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:50
DataPoint Verified.		04 Mar 2021 04:41:49
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	02 Feb 2021 16:21:17

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:59
DataPoint Verified.		04 Mar 2021 04:44:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '15 Jan 2021'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:21:43

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[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 20:11:59
DataPoint Verified.		04 Mar 2021 04:44:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:21:43

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

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 20:11:59
DataPoint Verified.		04 Mar 2021 04:44:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4)	
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 'Confirm positive' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 08:00:35
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 'Confirm positive' (Site from System).	Emily Carney (b) (4)	28 Jan 2021 16:55:46
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).	(b) (4)	
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	28 Jan 2021 16:51:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Carney (b) (4)	28 Jan 2021 16:51:33
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)	
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 by data change (Site from System).	System	28 Jan 2021 16:50:33
User entered 'No (N)' reason for change: Data Entry Error	System	28 Jan 2021 16:50:33
User closed query 'Data is required. Please complete.' (Site from System).	Emily Carney (b) (4)	28 Jan 2021 16:50:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 18:06:32
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	22 Jan 2021 18:06:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Fries (b) (4)	22 Jan 2021 18:06:32
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 18:21:43
User entered empty.	Jamie Fries (b) (4)	15 Jan 2021 18:21:43

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:59
DataPoint Verified.		04 Mar 2021 04:44:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '15 Jan 2021'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:21:43

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:59
DataPoint Verified.		04 Mar 2021 04:44:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:21:43

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:59
DataPoint Verified.		04 Mar 2021 04:44:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:21:43

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[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 20:11:59
DataPoint Verified.		04 Mar 2021 04:44:39
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:21:43

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 04:44:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	Jamie Fries (b) (4)	15 Jan 2021 18:21:43

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:59
DataPoint Verified.		04 Mar 2021 04:44:44
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:21:43

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:29:33

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:59
User entered '1'	System	28 Jan 2021 16:51:33
User entered '0'	System	28 Jan 2021 16:50:33
User entered '1'	System	22 Jan 2021 18:06:32

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

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 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
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	28 Jan 2021 18:24:53
User entered 'No (N)' reason for change: Data Entry Error	System	28 Jan 2021 18:24:53
User opened query 'Data is required. Please complete.' (Site from System).	Emily Carney (b) (4)	28 Jan 2021 18:24:53
User entered empty.	(b) (4)	
	System	28 Jan 2021 18:24:44
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

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 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	28 Jan 2021 18:24:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	Emily Carney (b) (4)	28 Jan 2021 18:24:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		22 Apr 2021 16:09:06
DataPoint Un-verified.		04 Mar 2021 04:47:42
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:29
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	28 Jan 2021 18:24:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		22 Apr 2021 16:09:09
DataPoint Un-verified.		04 Mar 2021 04:47:45
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '16 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	28 Jan 2021 18:24:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		22 Apr 2021 16:09:12
DataPoint Un-verified.		04 Mar 2021 04:47:52
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '16 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	28 Jan 2021 18:24:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	Emily Carney (b) (4)	28 Jan 2021 18:24:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	28 Jan 2021 18:24:44

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[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 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

US3802120

Folder: Covid-19 Assessment 15 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:29:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:09
DataPoint Verified.		04 Mar 2021 04:47:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4)	
	Emily Carney (b) (4)	28 Jan 2021 18:24:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:29:33

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:12:17
DataPoint Verified.		04 Mar 2021 04:49:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:21:56

US3802120

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:29:33

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
User accepted default value 'Day 3 (Day 3)'	Emily Carney (b) (4) (b) (4)	11 Feb 2021 20:54:07

US3802120

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:29:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:57:02
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4)	
	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:57:04
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:24
Signature has been broken.	(b) (4)	
	Emily Dougherty (b) (4)	19 Feb 2021 15:14:49
	(b) (4)	
User entered '17 Jan 2021' reason for change: Data Entry Error	Emily Dougherty (b) (4)	19 Feb 2021 15:14:49
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
	(b) (4)	
User entered '23 Dec 2020'	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:29:33

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
User accepted default value 'Day 5 (Day 5)'	Emily Carney (b) (4) (b) (4)	11 Feb 2021 20:54:07

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:29:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:57:22
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4)	
	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:57:24
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:24
Signature has been broken.	(b) (4)	
	Emily Dougherty (b) (4)	19 Feb 2021 15:14:49
	(b) (4)	
User entered '19 Jan 2021' reason for change: Data Entry Error	Emily Dougherty (b) (4)	19 Feb 2021 15:14:49
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
	(b) (4)	
User entered '25 Dec 2020'	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:29:33

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
User accepted default value 'Day 7 (Day 7)'	Emily Carney (b) (4) (b) (4)	11 Feb 2021 20:54:07

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:29:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:57:36
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4)	
	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:57:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:24
Signature has been broken.	(b) (4)	
	Emily Dougherty (b) (4)	19 Feb 2021 15:14:49
	(b) (4)	
User entered '21 Jan 2021' reason for change: Data Entry Error	Emily Dougherty (b) (4)	19 Feb 2021 15:14:49
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
	(b) (4)	
User entered '27 Dec 2020'	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:29:33

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
User accepted default value 'Day 9 (Day 9)'	Emily Carney (b) (4) (b) (4)	11 Feb 2021 20:54:07

US3802120

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:29:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:57:58
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4)	
	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:58:00
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:24
Signature has been broken.	(b) (4)	
	Emily Dougherty (b) (4)	19 Feb 2021 15:14:49
	(b) (4)	
User entered '23 Jan 2021' reason for change: Data Entry Error	Emily Dougherty (b) (4)	19 Feb 2021 15:14:49
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
	(b) (4)	
User entered '29 Dec 2020'	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:29:33

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
User accepted default value 'Day 14 (Day 14)'	Emily Carney (b) (4) (b) (4)	11 Feb 2021 20:54:07

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:29:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:58:15
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4)	
	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 06:58:17
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
	(b) (4)	
User entered '28 Jan 2021' reason for change: Data Entry Error	Emily Dougherty (b) (4)	11 Feb 2021 21:04:05
	(b) (4)	
User entered '3 Jan 2021'	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:29:33

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
User accepted default value 'Day 21 (Day 21)'	Emily Carney (b) (4) (b) (4)	11 Feb 2021 20:54:07

US3802120

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:29:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 07:06:31
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4)	
	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

US3802120

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Feb 2021 07:06:32
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
	(b) (4)	
User entered '04 Feb 2021' reason for change: Data Entry Error	Emily Dougherty (b) (4)	11 Feb 2021 21:05:27
	(b) (4)	
User entered '10 Jan 2021'	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:29:33

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
User accepted default value 'Day 28 (Day 28)'	Emily Carney (b) (4) (b) (4)	11 Feb 2021 20:54:07

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:29:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Apr 2021 14:46:15
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
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	17 Feb 2021 18:59:12
User entered 'Yes (Y)' reason for change: Data Entry Error	System	17 Feb 2021 18:59:12
User opened query 'Data is required. Please complete.' (Site from System).	Lisa Vavro (b) (4)	17 Feb 2021 18:59:12
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	System	11 Feb 2021 21:05:47
	Emily Dougherty (b) (4)	11 Feb 2021 21:05:47
	(b) (4)	
	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:58
DataPoint Verified.		22 Apr 2021 14:46:17
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
	(b) (4)	
User entered '17 Feb 2021' reason for change: Data Entry Error	Lisa Vavro (b) (4)	17 Feb 2021 18:59:46
	(b) (4)	
User entered empty; reason for change Data Entry Error	Emily Dougherty (b) (4)	11 Feb 2021 21:05:47
	(b) (4)	
User entered '20 Jan 2021'	Emily Carney (b) (4)	11 Feb 2021 20:54:07
	(b) (4)	

US3802120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:15
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:52:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	Jamie Fries (b) (4)	15 Jan 2021 18:13:08

US3802120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021, 19JAN2021, 21JAN2021 and 23JAN2021 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). DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 07:36:10 22 Feb 2021 06:52:38
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021, 19JAN2021, 21JAN2021 and 23JAN2021 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 'Confirmed dates and updated EDC' (Site from DM).	Emily Dougherty (b) (4) (b) (4)	19 Feb 2021 15:15:05
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021, 19JAN2021, 21JAN2021 and 23JAN2021 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)	04 Feb 2021 13:06:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '15 Jan 2021'	Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:13:08

US3802120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:15
DataPoint Verified.		22 Feb 2021 06:52:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Clinic (Clinic)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:13:08

US3802120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:15
User entered 'SICKD1'	System	15 Jan 2021 18:13:08

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:38
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '15 Jan 2021'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '12:13'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
User entered '15 Jan 2021 12:13'	System	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered missing code ND - Not Done.	(b) (4) Jamie Fries (b) (4)	15 Jan 2021 18:14:15
DataPoint set to visible.	(b) (4) System	15 Jan 2021 18:13:08

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:55:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered missing code ND - Not Done.	Jamie Fries (b) (4)	15 Jan 2021 18:14:15
DataPoint set to visible.	System	15 Jan 2021 18:13:08

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.6' F reason for change: Data Entry Error	System	15 Jan 2021 18:14:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Jamie Fries (b) (4)	15 Jan 2021 18:14:28
User entered '97.6' (non-conformant).	(b) (4)	
	System	15 Jan 2021 18:14:15
	Jamie Fries (b) (4)	15 Jan 2021 18:14:15
	(b) (4)	

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Other (Other)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'infrared'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '73'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
User entered 'bpm'	System	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:55:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '20'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
User entered 'breaths/min'	System	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:56:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '164'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
User entered 'mmHg'	System	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
DataPoint Verified.		22 Feb 2021 06:56:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '66'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26
User entered 'mmHg'	System	15 Jan 2021 18:14:15

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26

US3802120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:26

US3802120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:35
DataPoint Verified.		22 Feb 2021 06:56:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:51

US3802120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:35
DataPoint Verified.		22 Feb 2021 06:56:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '15 Jan 2021'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:14:51

US3802120

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:29:33

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:41
DataPoint Verified.		04 Mar 2021 04:50:18
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:24
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:15:26

US3802120

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:41
DataPoint Verified.		04 Mar 2021 04:50:21
User closed query 'Per GCL Lab Recon: SARS-CoV-2: Per Preclarus report, there is no record of this Subject ID US3802120 with SARS sample collected on "15 JAN 2021" , please kindly review if there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, as there is no record of this subject ID record in PPD GCL per Preclarus report. Thank you ' (Site from DM).		22 Feb 2021 10:47:16
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:24
	(b) (4)	
Query 'Per GCL Lab Recon: SARS-CoV-2: Per Preclarus report, there is no record of this Subject ID US3802120 with SARS sample collected on "15 JAN 2021" , please kindly review if there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, as there is no record of this subject ID record in PPD GCL per Preclarus report. Thank you ' answered with 'I answered this query before - we did collect blood from this participant but blood sample for illness visit was lost during transit between site and lab. This was added to deviation log. ' (Site from DM).	Emily Dougherty (b) (4)	19 Feb 2021 15:12:45
	(b) (4)	
User opened query 'Per GCL Lab Recon: SARS-CoV-2: Per Preclarus report, there is no record of this Subject ID US3802120 with SARS sample collected on "15 JAN 2021" , please kindly review if there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, as there is no record of this subject ID record in PPD GCL per Preclarus report. Thank you ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 11:17:22

US3802120

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per Lab Recon: SARS-COV2: Sample dated 15 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. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 11:16:30
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 15 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.	(b) (4), (b) (6)	29 Jan 2021 13:34:31
' (Site from DM). User entered '15 Jan 2021'	Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:15:26

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:54
DataPoint Verified.		22 Apr 2021 20:01:12
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:57:23

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:54
DataPoint Verified.		22 Apr 2021 20:01:12
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '17 Feb 2021'	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:57:23
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:54
DataPoint Verified.		22 Apr 2021 20:01:12
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Clinic (Clinic)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:57:23

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:54:54
User entered 'SICKD28'	System	17 Feb 2021 18:57:23

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:58:28
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '17 Feb 2021'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '11:17'	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:58:28
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
User entered '17 Feb 2021 11:17'	System	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered missing code ND - Not Done.	(b) (4) Lisa Vavro (b) (4)	17 Feb 2021 18:58:28
DataPoint set to visible.	(b) (4) System	17 Feb 2021 18:57:23

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered missing code ND - Not Done.	(b) (4) Lisa Vavro (b) (4)	17 Feb 2021 18:58:28
DataPoint set to visible.	(b) (4) System	17 Feb 2021 18:57:23

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '98.7' F	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Other (Other)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Infrared'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '55'	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:58:28
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
User entered 'bpm'	System	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '20'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
User entered 'breaths/min'	System	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '140'	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:58:28
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
User entered 'mmHg'	System	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
DataPoint Verified.		22 Apr 2021 20:01:37
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '88'	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:58:28
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09
User entered 'mmHg'	System	17 Feb 2021 18:58:28

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:09

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:26
DataPoint Verified.		22 Apr 2021 20:01:52
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'No (N)'	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:58:36
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:26
DataPoint Verified.		22 Apr 2021 20:01:52
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered empty.	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:58:36
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:29:33

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:39
DataPoint Verified.		22 Apr 2021 20:01:59
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4)	
	Lisa Vavro (b) (4)	17 Feb 2021 18:58:50
	(b) (4)	

US3802120

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:29:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:55:39
DataPoint Verified.		22 Apr 2021 20:01:59
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '17 Feb 2021'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:58:50

US3802120

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

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	07 Jan 2021 16:23:59

US3802120

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

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '7 Jan 2021'	(b) (4) Matthew Lee (b) (4)	07 Jan 2021 16:23:59

US3802120

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

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Clinic (Clinic)'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:23:59

US3802120

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

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 16:23:59

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '7 Jan 2021'	(b) (4) Matthew Lee (b) (4)	07 Jan 2021 16:24:10

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	08 Apr 2021 18:38:05
User entered '0'	(b) (4) Emily Carney (b) (4)	08 Apr 2021 17:47:13
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:28:02

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:10

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).		16 Apr 2021 01:38:21
User signature succeeded.	Judith Martin (b) (4)	08 Apr 2021 18:38:05
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	Emily Carney (b) (4)	08 Apr 2021 17:47:29
User entered 'Amendment 6 or later (Amendment 6 or later)'	Emily Carney (b) (4)	08 Apr 2021 17:47:13
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:55:30
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:28:02

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '7 Jan 2021'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:10

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Placebo (Placebo)'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:10

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:56:09
User entered 'Placebo (Placebo)'	Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:10

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:56:09
User entered 'Placebo (Placebo)'	Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:10

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:10

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '1'	System	07 Jan 2021 16:24:10

US3802120

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

Form: Unblinding

Generated On: 12 Aug 2021 13:29:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'I'	System	07 Jan 2021 16:24:10

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '60' in	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '191' lb	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '37.38013'	System	07 Jan 2021 17:24:38
DataPoint set to visible.	System	07 Jan 2021 16:24:10

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '60' in	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '191' lb	(b) (4) Emily Carney (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '37.38013'	System	07 Jan 2021 17:24:38
DataPoint set to visible.	System	07 Jan 2021 16:24:10

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '7 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '10:33'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '7 Jan 2021 10:33'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '99.2' F	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '60'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'bpm'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '18'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'breaths/min'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '160'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mmHg'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 08:53:14
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:47
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		07 Jan 2021 17:24:38
User entered '58'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mmHg'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '60' in	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '191' lb	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:29:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '37.38013'	System	07 Jan 2021 17:24:38
DataPoint set to visible.	System	07 Jan 2021 16:24:10

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '7 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '12:20'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '7 Jan 2021 12:20'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '99.4' F	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered 'Infrared'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '54'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'bpm'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '16'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'breaths/min'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '169'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mmHg'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '73'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:24:38

US3802120

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mmHg'	System	07 Jan 2021 17:24:38

US3802120

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	07 Jan 2021 16:24:21

US3802120

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '7 Jan 2021'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:21

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:22:18

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:22:18

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered empty.	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:22:18

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mRNA-1273'	System	07 Jan 2021 17:22:18
DataPoint set to visible.	System	07 Jan 2021 16:24:10

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '7 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:22:18

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:11:40
User entered '11:38'	Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:22:18

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '7 Jan 2021 11:38'	System	07 Jan 2021 17:22:18

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emily Carney (b) (4) (b) (4)	07 Jan 2021 17:22:18

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'ONCE'	System	07 Jan 2021 17:22:18

US3802120

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

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'INTRAMUSCULAR'	System	07 Jan 2021 17:22:18

US3802120

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	07 Jan 2021 16:24:35

US3802120

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 07JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 07JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:23:37
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 07JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 07JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:42:51
User entered '7 Jan 2021'	Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:35

US3802120

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '11:05'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:35

US3802120

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '7 Jan 2021 11:05'	System	07 Jan 2021 16:24:35

US3802120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	07 Jan 2021 16:24:46

US3802120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:29:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '7 Jan 2021'	(b) (4) Matthew Lee (b) (4)	07 Jan 2021 16:24:46

US3802120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:29:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '11:08'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:46

US3802120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:29:33

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '7 Jan 2021 11:08'	System	07 Jan 2021 16:24:46

US3802120

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

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4) (b) (4)	07 Jan 2021 16:24:53

US3802120

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

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'I'	System	07 Jan 2021 16:24:53

US3802120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	15 Jan 2021 16:13:48

US3802120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered '15 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	15 Jan 2021 16:13:48

US3802120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4) (b) (4)	15 Jan 2021 16:13:48

US3802120

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	15 Jan 2021 16:13:48

US3802120

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:40
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	15 Jan 2021 16:13:53

US3802120

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:52
User entered 'I'	System	15 Jan 2021 16:13:53

US3802120

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:52
User entered 'I'	System	15 Jan 2021 16:13:53
DataPoint set to visible.	System	15 Jan 2021 16:13:53

US3802120

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:53:37

US3802120

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '17 Feb 2021'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:53:37

US3802120

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Clinic (Clinic)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:53:37

US3802120

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'OLD29'	System	17 Feb 2021 18:53:37

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '17 Feb 2021'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '11:17'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '17 Feb 2021 11:17'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '98.7' F	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Other (Other)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Infrared'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '55'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'bpm'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '20'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'breaths/min'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '140'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mmHg'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '88'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mmHg'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '17 Feb 2021'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '12:41'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '17 Feb 2021 12:41'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '98.0' F	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Other (Other)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Infrared'	Lisa Vavro (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '54'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'bpm'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '20'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'breaths/min'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	19 Feb 2021 14:45:23
User entered '144'	Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mmHg'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4) (b) (4)	19 Feb 2021 14:45:23
User entered '88'	Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mmHg'	System	17 Feb 2021 18:56:08

US3802120

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'No (N)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:15

US3802120

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered empty.	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:15

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered empty.	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered empty.	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'mRNA-1273'	System	17 Feb 2021 18:56:36
DataPoint set to visible.	System	15 Jan 2021 16:13:53

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '17 Feb 2021'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered '12:13'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered '17 Feb 2021 12:13'	System	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'ONCE'	System	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:29:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 18:56:36

US3802120

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	17 Feb 2021 18:56:41

US3802120

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:50
User entered 'I'	System	17 Feb 2021 18:56:41

US3802120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:22:05
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	25 Feb 2021 16:09:35

US3802120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:22:05
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered '25 Feb 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	25 Feb 2021 16:09:35

US3802120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:22:05
User signature succeeded.	Judith Martin (b) (4) (b) (4)	03 Mar 2021 16:32:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	Emily Carney (b) (4) (b) (4)	25 Feb 2021 16:09:35

US3802120

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:29:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:22:05
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered 'Attempted three times and left two messages.'	Emily Carney (b) (4)	25 Feb 2021 16:09:35

US3802120

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:22:05
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	25 Feb 2021 16:09:48

US3802120

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:29:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:22:05
User entered 'I'	System	25 Feb 2021 16:09:48

US3802120

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:39:30

US3802120

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '23 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:39:30

US3802120

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[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 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Clinic (Clinic)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:39:30

US3802120

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:29:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User entered 'OLD57'	System	23 Mar 2021 18:39:30

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '23 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '14:11'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User entered '23 Mar 2021 14:11'	System	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '97.8' F	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '63'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User entered 'bpm'	System	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '20'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User entered 'breaths/min'	System	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '142'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User entered 'mmHg'	System	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	25 Mar 2021 17:59:13
User entered '66'	Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User entered 'mmHg'	System	23 Mar 2021 18:40:12

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34

US3802120

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:29:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34

US3802120

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:24

US3802120

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:29:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:24

US3802120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:46

US3802120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '23 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:46

US3802120

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '14:18'	(b) (4) Emily Carney (b) (4) (b) (4)	23 Mar 2021 18:40:46

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:29:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:34
User entered '23 Mar 2021 14:18'	System	23 Mar 2021 18:40:46

US3802120

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:29:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:31:54
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:43:14
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:45:23
User closed query 'Per CDM: Did Subject Test Positive For SARS-CoV-2 by RT-PCR?=YES, However no adverse event has been updated in the AE form. Kindly review and update the AE eCRF as appropriate. Thankyou.' (Site from DM).	(b) (4)	
Query 'Per CDM: Did Subject Test Positive For SARS-CoV-2 by RT-PCR?=YES, However no adverse event has been updated in the AE form. Kindly review and update the AE eCRF as appropriate. Thankyou.' answered with 'update AE form ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 10:13:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	11 Feb 2021 20:04:32
User opened query 'Per CDM: Did Subject Test Positive For SARS-CoV-2 by RT-PCR?=YES, However no adverse event has been updated in the AE form. Kindly review and update the AE eCRF as appropriate. Thankyou.' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	11 Feb 2021 19:24:53
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 08:10:15
	Jamie Fries (b) (4)	22 Jan 2021 18:12:31
	(b) (4)	
	Jamie Fries (b) (4)	22 Jan 2021 18:06:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Apr 2021 14:43:27
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:38
User entered 'USA-US098-2021-mRNA-1273-P301000002'	System	26 Feb 2021 20:41:32
User entered 'New'	(b) (4), (b) (6)	26 Feb 2021 20:41:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:04:18
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
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.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:36:55
Data point term sent to Coder	(b) (4)	
User entered 'Symptomatic COVID-19'	Coder Import (b) (4)	11 Feb 2021 19:36:55
	(b) (4)	
	System	11 Feb 2021 19:35:51
	Emily Dougherty (b) (4)	11 Feb 2021 19:34:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Apr 2021 14:43:29
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
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) (4), (b) (6)	25 Mar 2021 10:20:16
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 'confirmed this is a true infection - recorded as a MAAE' (Site from DM).	Emily Dougherty (b) (4) (b) (4)	23 Mar 2021 22:18:00
DataPoint Un-verified.	Emily Dougherty (b) (4) (b) (4)	23 Mar 2021 22:17:15
Signature has been broken.	Emily Dougherty (b) (4) (b) (4)	23 Mar 2021 22:17:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Dougherty (b) (4) (b) (4)	23 Mar 2021 22:17:15
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)	21 Mar 2021 14:30:44
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:04:23
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:30:44
User entered 'No (N)'	Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:04:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'No (N)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:04:58
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'Yes (Y)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:00
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '15 Jan 2021'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:02
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered empty.	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 19:34:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Apr 2021 14:43:32
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
DataPoint Un-verified.	(b) (4)	
	Emily Carney (b) (4)	23 Feb 2021 15:29:26
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	23 Feb 2021 15:29:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	23 Feb 2021 15:29:26
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:05:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
	(b) (4)	
User entered 'Yes (Y)'	Emily Dougherty (b) (4)	11 Feb 2021 19:34:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Apr 2021 14:43:34
User closed query 'PV Query: Per protocol, please consider updating event end date to reflect date symptoms resolved (per symptom log, 20 Jan 2021).' (Site from Safety).		01 Apr 2021 13:34:28
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
Query 'PV Query: Per protocol, please consider updating event end date to reflect date symptoms resolved (per symptom log, 20 Jan 2021).' answered with 'changed' (Site from Safety).	(b) (4)	
Signature has been broken.	Melissa Andrasko (b) (4)	31 Mar 2021 16:45:09
	(b) (4)	
	Melissa Andrasko (b) (4)	31 Mar 2021 16:41:57
	(b) (4)	
User entered '20 Jan 2021' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	31 Mar 2021 16:41:57
	(b) (4)	
User opened query 'PV Query: Per protocol, please consider updating event end date to reflect date symptoms resolved (per symptom log, 20 Jan 2021).' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 15:57:08
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
	(b) (4)	
DataPoint Un-verified.	Emily Carney (b) (4)	23 Feb 2021 15:29:26
	(b) (4)	
Signature has been broken.	Emily Carney (b) (4)	23 Feb 2021 15:29:26
	(b) (4)	
User entered '27 Jan 2021' reason for change: Data Entry Error	Emily Carney (b) (4)	23 Feb 2021 15:29:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:05:09
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
	(b) (4)	
User entered empty.	Emily Dougherty (b) (4)	11 Feb 2021 19:34:52
	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered empty.	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:16
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'No (N)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:24
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:27
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:29
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered empty.	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:31
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered empty.	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:31
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:05:36
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
	(b) (4)	
User entered empty.	Emily Dougherty (b) (4)	11 Feb 2021 19:34:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:33
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered empty.	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:38
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:40
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:43
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:45
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:48
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:05:50
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'None (NONE)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Apr 2021 14:43:40
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:37:31
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	Emily Carney (b) (4)	30 Mar 2021 17:25:55
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Emily Carney (b) (4)	30 Mar 2021 17:25:40
User entered '0' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	Emily Carney (b) (4)	30 Mar 2021 17:25:40
DataPoint Verified.	(b) (4), (b) (6)	21 Mar 2021 14:31:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:07:49
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '1' reason for change: Data Entry Error	(b) (4)	
User entered '0'	Emily Dougherty (b) (4)	11 Feb 2021 20:03:41
	(b) (4)	
	Emily Dougherty (b) (4)	11 Feb 2021 19:34:52
	(b) (4)	

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Apr 2021 14:43:41
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is FEVER. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).		07 Apr 2021 09:54:52
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is FEVER. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Emily Carney (b) (4) (b) (4)	06 Apr 2021 12:48:06
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is FEVER. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:08:45
User signature succeeded.	Judith Martin (b) (4) (b) (4)	31 Mar 2021 19:47:57
DataPoint Un-verified.	Emily Carney (b) (4) (b) (4)	30 Mar 2021 17:25:40
Signature has been broken.	Emily Carney (b) (4) (b) (4)	30 Mar 2021 17:25:40
User entered '1' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	30 Mar 2021 17:25:40
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:07:55
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:30:44
User entered '0' reason for change: Data Entry Error	Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 20:03:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:08:12
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Apr 2021 14:43:44
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
DataPoint Un-verified.	(b) (4)	
	Emily Carney (b) (4)	23 Feb 2021 15:29:26
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	23 Feb 2021 15:29:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Emily Carney (b) (4)	23 Feb 2021 15:29:26
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 06:08:22
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Emily Dougherty (b) (4)	11 Feb 2021 19:34:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
DataPoint Verified.		22 Feb 2021 06:08:24
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered empty.	(b) (4) Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:36
DataPoint Un-verified.		26 Apr 2021 17:11:31
User closed query 'PV Query: Treatment medication 'Advil' is indicated for fever. Per symptom log, chills are reported, but no fever. Please clarify.' (Site from Safety).		01 Apr 2021 13:34:45
Query 'PV Query: Treatment medication 'Advil' is indicated for fever. Per symptom log, chills are reported, but no fever. Please clarify.' answered with 'recorded as per participant report' (Site from Safety).	Melissa Andrasko (b) (4) (b) (4)	31 Mar 2021 16:45:36
User opened query 'PV Query: Treatment medication 'Advil' is indicated for fever. Per symptom log, chills are reported, but no fever. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 15:58:41
DataPoint Verified.		22 Feb 2021 06:08:26
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:30:44
User entered empty.	Emily Dougherty (b) (4) (b) (4)	11 Feb 2021 19:34:52

US3802120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Feb 2021 19:34:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:29:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 22:17:15
User entered '0'	System	11 Feb 2021 19:34:52

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:29:33

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:31:54
DataPoint Verified.		22 Apr 2021 14:44:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:14:48

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:07:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 20:58:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 20:58:40
Data point term sent to Coder Coding entries removed.	System Melissa Andrasko (b) (4) (b) (4)	13 Nov 2020 20:57:36 13 Nov 2020 20:56:53
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:16:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:16:42
Data point term sent to Coder User entered 'Fenofibrate'	System Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:16:02 03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:07:29
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:08:43
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
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) (6)	18 Nov 2020 12:30:31
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:30:15
Signature has been broken.	Melissa Andrasko (b) (4)	13 Nov 2020 20:56:53
User entered 'elevated TRIGLYCERIDES' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	13 Nov 2020 20:56:53
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 'Per participant report medication is being taken for triglycerides. Participant did not list condition in medical history.' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 20:56:10
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'participant did not report condition on medical history' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 20:54:18
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 05:11:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	11 Nov 2020 00:39:50
	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Triglycerides'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:15:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:08:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	22 Oct 2020 19:44:36
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
	(b) (4)	
User entered '145'	Dominic Kramer (b) (4)	03 Sep 2020 14:15:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:08:48
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'mg (mg)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:08:50
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:08:52
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'once daily (QD)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:08:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:00
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Oral (ORAL)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:04
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:11
DataPoint Un-verified.		22 Apr 2021 20:09:08
DataPoint Verified.		22 Apr 2021 20:09:06
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'UN UNK 2008'	(b) (4) Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:09
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:13
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:15
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:30:36
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 20:56:34
Signature has been broken.	Melissa Andrasko (b) (4)	13 Nov 2020 20:53:35
User entered 'No (N)' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	13 Nov 2020 20:53:35
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 00:40:48
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	03 Sep 2020 14:15:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:15:59

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:29:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:15:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:34
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
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.	Coder Import (b) (4)	03 Sep 2020 14:18:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 14:18:47
Data point term sent to Coder	System	03 Sep 2020 14:18:09
User entered 'Levothyroxine'	Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:37
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:39
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Hypothyroidism'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:42
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '100'	Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
Signature has been broken.	Emily Dougherty (b) (4)	12 Nov 2020 12:28:54
User entered 'ug (ug)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	12 Nov 2020 12:28:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Other (OTHER)'	Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 12:30:40
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'updated to ug' (Site from DM).	Emily Dougherty (b) (4) (b) (4)	12 Nov 2020 12:29:01
Signature has been broken.	Emily Dougherty (b) (4) (b) (4)	12 Nov 2020 12:28:54
User entered empty; reason for change Data Entry Error	Emily Dougherty (b) (4) (b) (4)	12 Nov 2020 12:28:54
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:32:26
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:32:26
User entered 'Mcg'	Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:55
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'once daily (QD)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:09:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:02
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Oral (ORAL)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:04
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:06
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'UN UNK 1985'	Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:08
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:11
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:13
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:30:43
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated to say no' (Site from DM).	Emily Dougherty (b) (4)	12 Nov 2020 12:29:16
Signature has been broken.	(b) (4)	12 Nov 2020 12:29:10
User entered 'No (N)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	12 Nov 2020 12:29:10
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 00:43:20
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:29:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:17:57

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:41
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 14:20:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 14:20:47
Data point term sent to Coder	System	03 Sep 2020 14:19:11
User entered 'Pantoprazole'	Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:44
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:47
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'GERD'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:52
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '40'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:56
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'mg (mg)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:59
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:01
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'once daily (QD)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:09
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:07
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Oral (ORAL)'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:12
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'UN UNK 2019'	(b) (4) Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:19
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered '0'	(b) (4) Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:29
DataPoint Un-verified.		22 Apr 2021 20:11:26
DataPoint Verified.		22 Apr 2021 20:11:24
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:31
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered empty.	Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:11:38
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:30:49
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Emily Dougherty (b) (4)	12 Nov 2020 12:30:45
Signature has been broken.	(b) (4)	12 Nov 2020 12:30:40
User entered 'No (N)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	12 Nov 2020 12:30:40
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 00:43:49
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:32:26
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:29:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:19:08

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
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, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:37:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:37:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	06 Apr 2021 15:48:59
Data point term sent to Coder	System	06 Apr 2021 12:49:35
User closed query 'CDM-Coding: The trade name ADVIL can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	06 Apr 2021 12:49:21
Query 'CDM-Coding: The trade name ADVIL can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'updated' (Site from System).	Emily Carney (b) (4) (b) (4)	06 Apr 2021 12:49:21
Signature has been broken.	Emily Carney (b) (4) (b) (4)	06 Apr 2021 12:49:06
User entered 'ADVIL (ibuprofen)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	06 Apr 2021 12:49:06
User opened query 'CDM-Coding: The trade name ADVIL can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:29:42
Data point term sent to Coder	System	06 Apr 2021 12:22:07
Coding entries removed.	Emily Carney (b) (4) (b) (4)	06 Apr 2021 12:21:55

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EAB) (1725)

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US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
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, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 18:28:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 18:28:07
Data point term sent to Coder	System	15 Jan 2021 18:27:17
Data point term sent to Coder	System	15 Jan 2021 18:26:15
User entered 'Advil'	Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'No (N)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	06 Apr 2021 15:48:59
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	06 Apr 2021 12:21:55
	(b) (4)	
User entered 'FEVER due to symptomatic covid'	Emily Carney (b) (4)	06 Apr 2021 12:21:55
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
	(b) (4)	
User entered 'Fever'	Jamie Fries (b) (4)	15 Jan 2021 18:26:09
	(b) (4)	

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '200'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'mg (mg)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered 'as needed (PRN)'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
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	15 Jan 2021 18:26:23
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Jamie Fries (b) (4)	15 Jan 2021 18:26:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Jan 2021 18:26:09
	Jamie Fries (b) (4)	15 Jan 2021 18:26:09
	(b) (4)	

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the associated AE. Please review and reconcile the Con Med and AE start dates if applicable. If FEVER is not associated with AE, please add a medical condition and all applicable details on AE eCRF. Otherwise, provide clarification for this occurrence. ' (Site from DM).		04 Mar 2021 15:05:16
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Query 'Per DM CLR: Con Med start date is prior to the start date of the associated AE. Please review and reconcile the Con Med and AE start dates if applicable. If FEVER is not associated with AE, please add a medical condition and all applicable details on AE eCRF. Otherwise, provide clarification for this occurrence. ' answered with 'updated to correspond with AE' (Site from DM).	Emily Carney (b) (4)	23 Feb 2021 18:15:21
Signature has been broken.	Emily Carney (b) (4)	23 Feb 2021 18:14:55
User entered '15 Jan 2021' reason for change: Data Entry Error	Emily Carney (b) (4)	23 Feb 2021 18:14:55
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the associated AE. Please review and reconcile the Con Med and AE start dates if applicable. If FEVER is not associated with AE, please add a medical condition and all applicable details on AE eCRF. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:13:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '14 Jan 2021'	Jamie Fries (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
User entered '0'	(b) (4) Jamie Fries (b) (4) (b) (4)	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	23 Feb 2021 18:16:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4)	23 Feb 2021 18:16:00
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 18:26:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 18:26:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Fries (b) (4)	15 Jan 2021 18:26:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 18:26:09
User entered empty.	Jamie Fries (b) (4)	15 Jan 2021 18:26:09
	(b) (4)	

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	23 Feb 2021 18:16:00
	(b) (4)	
User entered '23 Jan 2021' reason for change: Data Entry Error	Emily Carney (b) (4)	23 Feb 2021 18:16:00
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:11:29
	(b) (4)	
User entered empty.	Jamie Fries (b) (4)	15 Jan 2021 18:26:09
	(b) (4)	

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' (Site from DM).		04 Mar 2021 15:05:31
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4)	
Signature has been broken.	Emily Carney (b) (4)	23 Feb 2021 18:15:29
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4)	23 Feb 2021 18:14:55
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	23 Feb 2021 06:09:28
User entered 'Yes (Y)'	Judith Martin (b) (4)	01 Feb 2021 16:11:29
	(b) (4)	
	Jamie Fries (b) (4)	15 Jan 2021 18:26:09
	(b) (4)	

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User entered empty.	System	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User entered empty.	System	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:29:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:29:10
User entered empty.	System	15 Jan 2021 18:26:09

US3802120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:29:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:47
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:30:44
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	08 Feb 2021 13:51:30

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'USA-US098-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Judith'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Martin'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '3420 Fifth Ave'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Pittsburgh'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'PA'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '15213'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:41:23
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
	(b) (4)	
User entered 'US'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 13:36:19
User entered '3'	System	31 Mar 2021 16:39:26
User entered '2'	System	24 Mar 2021 13:41:41
User entered '1'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'USA-US098-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Judith'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Martin'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '3420 Fifth Ave'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Pittsburgh'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'PA'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '15213'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
Reviewed for Safety.		24 Mar 2021 13:41:23
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered 'US'	(b) (4) System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 13:36:19
User entered '3'	System	31 Mar 2021 16:39:26
User entered '2'	System	24 Mar 2021 13:41:41
User entered '1'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:29:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
User entered '26/Feb/2021 14:42'	(b) (4) System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:29:33

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)	22 Apr 2021 14:42:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:41:23
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'USA-US098-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Judith'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Martin'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '3420 Fifth Ave'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Pittsburgh'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'PA'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '15213'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:41:23
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
	(b) (4)	
User entered 'US'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 13:36:19
User entered '3'	System	31 Mar 2021 16:39:26
User entered '2'	System	24 Mar 2021 13:41:41
User entered '1'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:29:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
User entered '24/Mar/2021 09:41'	(b) (4) System	24 Mar 2021 13:41:41

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:29:33

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)	22 Apr 2021 14:42:41
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 13:35:45
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:59:13
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 13:41:41

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'USA-US098-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Judith'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Martin'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '3420 Fifth Ave'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Pittsburgh'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'PA'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '15213'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:41:23
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
	(b) (4)	
User entered 'US'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 13:36:19
User entered '3'	System	31 Mar 2021 16:39:26
User entered '2'	System	24 Mar 2021 13:41:41
User entered '1'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:29:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered '31/Mar/2021 09:39'	(b) (4) System	31 Mar 2021 16:39:26

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:29:33

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)	22 Apr 2021 14:42:41
Reviewed for Safety.		01 Apr 2021 13:35:45
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:47:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:26

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'USA-US098-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'No (N)'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Judith'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Martin'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '3420 Fifth Ave'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'Pittsburgh'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered 'PA'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:59
User entered '15213'	System	26 Feb 2021 20:41:32

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:41:23
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:32:52
	(b) (4)	
User entered 'US'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:29:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 13:36:19
User entered '3'	System	31 Mar 2021 16:39:26
User entered '2'	System	24 Mar 2021 13:41:41
User entered '1'	System	26 Feb 2021 20:42:08

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:29:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	01 Apr 2021 19:12:30
User entered '01/Apr/2021 09:36'	(b) (4) System	01 Apr 2021 13:36:19

US3802120

Folder: SAE USA-US098-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:29:33

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)	22 Apr 2021 14:42:41
User signature succeeded.	Judith Martin (b) (4)	01 Apr 2021 19:12:30
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 13:36:19