

US3602111 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:59:25

All time stamps listed in this document are displayed in GMT

US3602111

Form: Participant Creation

Data signed: (b) (4) 19 Mar 2021 17:48:26

Generated On: 11 Aug 2021 22:59:25

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[Participant ID](#)

US3602111

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

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US3602111

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Date of Birth (MMM yyyy)	(b) (6) 1984
Age	36
Age Units	YEARS
Age (Derived)	36
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Date of Informed Consent ( <i>dd MMM yyyy</i> )	29 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) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Mar 2021 17:48:34

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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) 19 Mar 2021 17:48:34

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Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Mar 2021 17:48:34

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Condition	BILATERAL TUBAL LIGATION
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 17:48:34

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	8:53 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 8:53
Height (xxx.x)	66 in
Weight (xxx.x)	166 lb
BMI (xxx.x)	26.84912 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:48:34

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 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) 19 Mar 2021 17:48:33

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Date of assessment (*dd MMM yyyy*) 29 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*) UN UNK 2015

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 17:48:34

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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**

(b) (6)

REGISTRANT

**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) 19 Mar 2021 17:48:34

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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) 19 Mar 2021 17:48:34

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What was the date of randomization? (dd MMM yyyy) 29 SEP 2020

What was the participant's randomization number? 115708

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) 19 Mar 2021 17:48:34

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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) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

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)	29 SEP 2020
Time of assessment (00:00-23:59)	8:53 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 8:53
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 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) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

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)	29 SEP 2020
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:48
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:48:34

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Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 10:15

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) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

9:45 (24 HR)

Collection date and time (derived)

29 SEP 2020 9:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:45	29 SEP 2020 9:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

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: 11 Aug 2021 22:59:25

**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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 10:50

PC Open Date & Time

29 SEP 2020 10:35

PC Close Date & Time

29 SEP 2020 13:05

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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	29 SEP 2020 23:20
PC Open Date & Time	29 SEP 2020 14:00
PC Close Date & Time	30 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:25

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**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 22:58

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:25

**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

97.7 °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

02 OCT 2020 03:50

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 06:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:25

**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

99.3 °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

04 OCT 2020 08:53

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 05:17

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:25

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.8 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

05 OCT 2020 22:34

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PC Open Date & Time

05 OCT 2020 12:00

---

PC Close Date & Time

06 OCT 2020 11:59

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US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

**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

29 SEP 2020 10:51

PC Open Date & Time

29 SEP 2020 10:35

PC Close Date & Time

29 SEP 2020 13:05

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

**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

29 SEP 2020 23:21

PC Open Date & Time

29 SEP 2020 14:00

PC Close Date & Time

30 SEP 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:25

**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

30 SEP 2020 22:58

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:25

**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

02 OCT 2020 03:50

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:25

**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

03 OCT 2020 06:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:25

**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

04 OCT 2020 08:53

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:25

**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

05 OCT 2020 05:18

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:25

**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

05 OCT 2020 22:35

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

**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 ☐

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:51
PC Open Date & Time	29 SEP 2020 10:35
PC Close Date & Time	29 SEP 2020 13:05

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

**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 ☐

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 23:21
PC Open Date & Time	29 SEP 2020 14:00
PC Close Date & Time	30 SEP 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:25

**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: 11 Aug 2021 22:59:25

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 22:58
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:25

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:25

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 03:50
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:25

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 ☒

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:25

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 06:39
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:25

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:25

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 08:53
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:25

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: 11 Aug 2021 22:59:25

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 05:18
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:25

**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 ☒

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:25

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 22:35
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3602111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

8:38 PM AND 9:10 PM - CALLED  
TWICE WITHOUT SUCCESS.  
VOICE MAILBOX IS FULL AND  
WAS UNABLE TO LEAVE A  
MESSAGE.

*If Contact Not Made, please provide Comments*

US3602111

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

*If Contact Not Made, please provide Comments*

CALLED SUBJECT ON 10/13 AT  
21:09H FOR SCD15, NO  
RESPONSE, LEFT VM TO CALL  
BACK.  
CALLED SUBJECT ON 10/14 AT  
11:00H, NO RESPONSE, LEFT VM  
TO CALL BACK. SUBJECT DID  
NOT CALL BACK, CONTACT  
NOT MADE.

US3602111

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3602111

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3602111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:25

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

US3602111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:25

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

US3602111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:25

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.*

US3602111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:25

Was study treatment given? Yes ☐  
No ☐

If No, reason not given

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

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

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

**US3602111**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

**US3602111**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:59:25**

Collection date ( <i>dd MMM yyyy</i> )			
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			



US3602111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

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

SUBJECT WAS IN  
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3602111

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

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

SUBJECT WAS IN  
CONVALESCENT PERIOD

*If Contact Not Made, please provide Comments*

US3602111

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

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

SUBJECT WAS IN  
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3602111

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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



US3602111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 NOV 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	30 NOV 2020 08:20
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	TEMPORAL
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 NOV 2020

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

US3602111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 NOV 2020

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

30 NOV 2020 08:20

US3602111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:34

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 08:33:24
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 12:00:23
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 07:06:48
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 00:01:49
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59



US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 00:56:51
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 00:01:22
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 00:02:23

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 00:01:37
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 01:13:16

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 00:33:50
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 00:03:32

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

**US3602111**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 22:59:25**

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



US3602111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

SUBJECT RETURNED CALL ON

12/24

*If Contact Not Made, please provide Comments*

US3602111

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LVMTCB --1/25 ( 5PM), 1/26  
(7:05PM) AND 1/27 (4PM)

*If Contact Not Made, please provide Comments*

US3602111

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

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

US3602111

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Mar 2021 17:48:31

Generated On: 11 Aug 2021 22:59:25

Date of Contact	26 OCT 2020
Time of Contact	14:29
Date and Time of Contact (derived)	26 OCT 2020 14:29
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>

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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"/>



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	101 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input 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 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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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Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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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Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

Date	1 NOV 2020
------	------------

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

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

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

Temperature	98 F
-------------	------

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

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

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

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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	3 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

Symptom Day

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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	4 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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	5 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 26 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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	6 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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 26 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 ☐

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

Symptom Day

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



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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	7 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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 26 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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 ☐

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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	8 NOV 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

Symptom Day

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



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

	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	9 NOV 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 27 Apr 2021 03:59:13

Generated On: 11 Aug 2021 22:59:25

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Mar 2021 17:48:27

Generated On: 11 Aug 2021 22:59:25

Date of Visit 27 OCT 2020

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

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

Date of Test 27 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Mar 2021 17:48:31

Generated On: 11 Aug 2021 22:59:25

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

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

Start Date \_\_\_\_\_

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Mar 2021 17:48:31

Generated On: 11 Aug 2021 22:59:25

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Mar 2021 17:48:31

Generated On: 11 Aug 2021 22:59:25

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Mar 2021 17:48:32

Generated On: 11 Aug 2021 22:59:25

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---



**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 19 Mar 2021 17:48:33

**Generated On: 11 Aug 2021 22:59:25**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 OCT 2020
Day 5	Yes	31 OCT 2020
Day 7	Yes	2 NOV 2020
Day 9	Yes	4 NOV 2020
Day 14	Yes	09 NOV 2020
Day 21	Yes	16 NOV 2020
Day 28	Yes	23 NOV 2020

US3602111

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	8:02 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 8:02
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602111

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3602111

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 OCT 2020

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:48:27

Generated On: 11 Aug 2021 22:59:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	SICKD28

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 17:48:27

Generated On: 11 Aug 2021 22:59:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	8:35 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 8:35
Height (xxx.x)	66 in
Weight (xxx.x)	164 lb
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	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:48:27

Generated On: 11 Aug 2021 22:59:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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



US3602111

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 19 Mar 2021 17:48:27

Generated On: 11 Aug 2021 22:59:25

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

**US3602111**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3602111

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

Form: Unblinding

Generated On: 11 Aug 2021 22:59:25

Date of updated informed consent ( <i>dd MMM yyyy</i> )		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
Was the participant unblinded?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5	<input type="checkbox"/>
	Amendment 6 or later	<input type="checkbox"/>
Date of unblinding ( <i>dd MMM yyyy</i> )		
Participant randomization assignment	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
Actual Dose 1	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Actual Dose 2	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Will participant receive mRNA-1273?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Placebo Only Flag		
Continuing with mRNA-1273		

**US3602111**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3602111**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:59:25**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00 - 23:59</i> )	<hr/>
Collection Date and Time (derived)	<hr/>

US3602111

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 00:02:10

Generated On: 11 Aug 2021 22:59:25

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 23:41:37

Generated On: 11 Aug 2021 22:59:25

AEID

Adverse event

SWEATING

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 23:41:37

Generated On: 11 Aug 2021 22:59:25

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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Mar 2021 23:41:37

Generated On: 11 Aug 2021 22:59:25

AEID	USA-US079-2020-MRNA-1273-P30 1000003
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)	24 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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 (7)

Data signed: (b) (4) 13 Mar 2021 23:41:37

Generated On: 11 Aug 2021 22:59:25

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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	
SUBJECT WAS EXPOSED TO COVID+ PATIENT ON 10/23/2020	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Mar 2021 17:48:27

Generated On: 11 Aug 2021 22:59:25

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

Yes ☒

No ☐

---

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

---

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1993	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Name of Medication CENTRUM

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication FEVER

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

	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)		24 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication FEVER

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

	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)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Name of Medication PFIZER COVID-19 VACCINE  
(NON-STUDY EUA)

Prophylaxis Yes ☒  
No ☐

Indication COVID-19

Dose per administration 0.3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	13 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)		13 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"/>

US3602111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 17:48:27

Generated On: 11 Aug 2021 22:59:25

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Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

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US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

### Case Report Form

Visit Date	True
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	True
Physical Examination	True
Central Laboratory - Nasopharyngeal Swab	True
Childbearing Potential	False
Pregnancy Test	True
Randomization	False
Exposure	True
Immunogenicity Assessment	True
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	27 OCT 2020
<b>Category</b>	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	True
Missed Visit	True
Missed Assessment	True
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
<b>Description of Relationship to COVID-19</b>	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3602111

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

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Date of dosing discontinuation (dd MMM yyyy)	27 NOV 2020
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---

Primary reason for dosing discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Due to SARS-COV-2 <input checked="" type="checkbox"/>
	Other <input type="checkbox"/>

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SAE
	USA-US079-2020-MRNA-1273-P30
	1000003 (LOG LINE 7)

---

US3602111

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 05 Apr 2021 21:12:08

Generated On: 11 Aug 2021 22:59:25

Date of study discontinuation/completion (dd MMM yyyy) 6 FEB 2021

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 checked="" 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

RECEIVED NON-STUDY EUA  
PFIZER COVID-19 VACCINE ON  
13/JAN/2021 OUTSIDE OF THE  
CLINICAL TRIAL

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"/>

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

SAEID	USA-US079-2020-MRNA-1273-P301000003
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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

SAEID	USA-US079-2020-MRNA-1273-P301000003
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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/NOV/2020 19:00
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



US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

SAEID	USA-US079-2020-MRNA-1273-P301000003
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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/NOV/2020 00:29
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

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Mar 2021 17:48:33

Generated On: 11 Aug 2021 22:59:25

SAEID	USA-US079-2020-MRNA-1273-P301000003
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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/NOV/2020 07:47
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

US3602111 (Prod: Hackensack University Medical Center)

**US3602111**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:59:25**

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:20:09
User entered 'US3602111'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 12:52:49

**US3602111**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:59:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:05:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:07:47

**US3602111**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:05:13
User entered '29 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 12:52:50

**US3602111**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:05:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Sep 2020 14:07:47



**US3602111**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'SCRN'	System	29 Sep 2020 14:07:47

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:09:08
User entered (b) (6) 1984'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 12:52:51

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:09:13
User entered '36'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'YEARS'	System	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '36'	System	29 Sep 2020 14:08:24

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:09:11
User entered 'Female (F)'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:12:38
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:12:45
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 14:08:11



**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:12:46
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:12:49
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:12:51
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:12:55
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:12:57
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:01
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:03
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

**US3602111**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:25**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:06
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11



**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:30
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:08:24

**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'Sep 2020'	System	29 Sep 2020 14:08:24

**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '2020'	System	29 Sep 2020 14:08:24

**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:30
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	29 Sep 2020 14:08:24

**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:08:24

**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:30
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:08:24

**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:30
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:08:24

**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:30
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:08:24



**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:30
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 12:52:50

**US3602111**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:25**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'I'	System	29 Sep 2020 14:08:35

**US3602111**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 22:59:25**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:08:35

**US3602111**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 22:59:25**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:13:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:08:59

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:14:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:11:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:11:53
Data point term sent to Coder	System	29 Sep 2020 14:10:55
User entered 'Asthma'	(b) (4), (b) (6)	29 Sep 2020 14:09:54

**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:14:04
User entered 'UN UNK 1993'	(b) (4), (b) (6)	29 Sep 2020 14:09:54

**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:14:04
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:09:54

**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:14:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:09:54



**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:14:04
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:09:54

**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:14:04
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:09:54

**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'Jan 1993'	System	29 Sep 2020 14:09:54

**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '1993'	System	29 Sep 2020 14:09:54

**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered empty.	System	29 Sep 2020 14:09:54

**US3602111**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered empty.	System	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 17:00:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 17:00:02
Data point term sent to Coder	System	11 Jan 2021 16:59:11
User entered 'Bilateral Tubal Ligation'	(b) (4), (b) (6)	11 Jan 2021 16:58:18

**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:58:18



**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:58:18

**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:58:18

**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:58:18

**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:58:18

**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'Jan 2015'	System	11 Jan 2021 16:58:18

**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '2015'	System	11 Jan 2021 16:58:18

**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'Jan 2015'	System	11 Jan 2021 16:58:18

**US3602111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '2015'	System	11 Jan 2021 16:58:18



US3602111

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:59:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Abdominal therapeutic procedures NEC, PT: Abdominoplasty, LLT: Abdominoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 17:01:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 17:01:02
Data point term sent to Coder	System	11 Jan 2021 17:00:11
User entered 'Abdominoplasty'	(b) (4), (b) (6)	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'Jan 2017'	System	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '2017'	System	11 Jan 2021 16:59:35



**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'Jan 2017'	System	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '2017'	System	11 Jan 2021 16:59:35

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered '8:53'	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '29 Sep 2020 8:53'	System	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered '66' in	(b) (4), (b) (6)	29 Sep 2020 14:10:46
DataPoint set to visible.	System	29 Sep 2020 14:08:35

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered '166' lb	(b) (4), (b) (6)	29 Sep 2020 14:10:46
DataPoint set to visible.	System	29 Sep 2020 14:08:35



**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered '26.84912'	System	29 Sep 2020 14:10:46
DataPoint set to visible.	System	29 Sep 2020 14:08:35

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'kg/m2'	System	29 Sep 2020 14:10:46
DataPoint set to visible.	System	29 Sep 2020 14:08:35

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'bpm'	System	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46



**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'breaths/min'	System	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'mmHg'	System	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:21:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered 'mmHg'	System	29 Sep 2020 14:10:46

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04

**US3602111**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04

**US3602111**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:59:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:22:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:10:53



**US3602111**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:59:25**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:22:43
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:10:53

**US3602111**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:17:36
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:11:05

**US3602111**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:20:47
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:17:09
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:17:09
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 16:17:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:25

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:39:48
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:59:46
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 03:11:06
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:20:47
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	21 Dec 2020 20:17:17
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:17:17
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:17:17
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	21 Dec 2020 20:17:09
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 16:17:36

**US3602111**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:25**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:05

**US3602111**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:25**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:17:36
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:20:47
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	21 Dec 2020 20:17:26
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:17:26
User entered 'UN UNK 2015' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:17:26
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	21 Dec 2020 20:17:17
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 16:17:36
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:05

**US3602111**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:25**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:17:36
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:11:05



**US3602111**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:17:36
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:05

**US3602111**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:25**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:17:36
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:11:05

**US3602111**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:20:32
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:17:53
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:17:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 16:25:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

**US3602111**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:20:32
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:17:53
User entered empty; reason for change New Information	(b) (4), (b) (6)	21 Dec 2020 20:17:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 16:25:14
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

**US3602111**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:20:32
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:17:53
User entered empty; reason for change New Information	(b) (4), (b) (6)	21 Dec 2020 20:17:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 16:25:14
User entered 'Urine (URINE)'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:25

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:20:32
User closed query 'CRA unable to verify pregnancy test resulg.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 20:20:30
Query 'CRA unable to verify pregnancy test resulg.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 20:17:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	21 Dec 2020 20:17:53
User opened query 'CRA unable to verify pregnancy test resulg.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 18:40:12
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 18:23:30
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 16:25:14
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

**US3602111**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:25:14
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

**US3602111**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:25:14
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:19



**US3602111**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:25:14
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:19

**US3602111**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User entered empty.	System	29 Sep 2020 14:11:19

**US3602111**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:59:25**

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

**US3602111**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:59:25**

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

**US3602111**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:59:25**

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

[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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04



US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

[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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

[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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

**US3602111**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:59:25**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered (b) (6) Registrant'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	(b) (4) System	30 Sep 2020 21:05:26
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	29 Sep 2020 14:20:04
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04



**US3602111**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:59:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

**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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

[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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:25

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 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

**US3602111**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:59:25**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:05:26
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

**US3602111**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:59:25**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:20:04

**US3602111**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:59:25**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:04
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:15:55
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:20:04

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:25:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:20:15



**US3602111**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:25:44
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:20:15

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:25:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Sep 2020 14:20:15

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'VISIT1'	System	29 Sep 2020 14:20:15

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered '29 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:07:55

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:25

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered '115708'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:07:55

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:25

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:07:55

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:25

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)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:59:25**

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)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29



**US3602111**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:59:25**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:59:25**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:59:25**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:59:25**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:26:22
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29
DataPoint set to visible.	System	29 Sep 2020 14:08:24

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:59:25**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:59:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:59:25**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:59:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35



**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '8:53'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered '29 Sep 2020 8:53'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '98.1' F	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35



**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '61'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'bpm'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '16'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'breaths/min'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '107'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'mmHg'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '69'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'mmHg'	System	29 Sep 2020 14:21:35



**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:59:25**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:59:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 15:12:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 15:12:23
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 14:21:35
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '29 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '10:48' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered '29 Sep 2020 10:48'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '99' F reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35



**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered 'Oral (Oral)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:57:23
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 18:56:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '73' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'bpm'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '16' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'breaths/min'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '104' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'mmHg'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35



US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:56:24
User entered '68' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'mmHg'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:59:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:40:47
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:21:43

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:59:25**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:40:47
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:43

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:01
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:21:47

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:01
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:01
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:01
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47



US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:25

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:01
User closed query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:16:02
Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:12:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 16:12:53
User opened query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:16:04
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:01
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:01
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered empty.	System	29 Sep 2020 14:21:47

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:25**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:08

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:25**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:59
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:25

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)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:59
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:22:08

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:25**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 14:22:08



US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:59
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:22:08

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:25**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:59
User entered '10:15'	(b) (4), (b) (6)	29 Sep 2020 14:22:08

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:25**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered '29 Sep 2020 10:15'	System	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:41:59
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	29 Sep 2020 14:22:08

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:25**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:41:59
User entered 'ONCE'	System	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:22:20

US3602111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:22:20



**US3602111**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '9:45'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:22:20

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered '29 Sep 2020 9:45'	System	29 Sep 2020 14:22:20

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:59:25**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:22:33

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:42:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:42:52
User entered '9:45'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered '29 Sep 2020 9:45'	System	29 Sep 2020 14:22:33

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Sep 2020 14:22:33



US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:22:33

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:59:25**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:22:33

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered empty.	System	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:59:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:42:58
User closed query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:40:24
Query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' answered with 'Subject is now in the convalescent period following positive COVID-19 results. However, since the positive result is after the completed safety calls, this will remain yes and under safety call Day 22 continuing that will be changed to no. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:40:11
User opened query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:05:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:40

**US3602111**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'I'	System	29 Sep 2020 14:22:40

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:26', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7ba34cbe-e67b-4893-b16b-c1bb29647128' User entered 'Yes (Y)'	System	29 Sep 2020 14:50:52
	System	29 Sep 2020 14:50:52

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:33', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7ba34cbe-e67b-4893-b16b-c1bb29647128' User entered '99.0'	System	29 Sep 2020 14:50:52
	System	29 Sep 2020 14:50:52



US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:38', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7ba34cbe-e67b-4893-b16b-c1bb29647128'	System	29 Sep 2020 14:50:52
User entered 'No (N)'	System	29 Sep 2020 14:50:52

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:42', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7ba34cbe-e67b-4893-b16b-c1bb29647128' User entered '29 Sep 2020 10:50'	System	29 Sep 2020 14:50:52
	System	29 Sep 2020 14:50:52

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 10:35'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 13:05'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:20:46', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'af392203-5976-44a2-ac88-10188b073591' User entered 'Yes (Y)'	System	30 Sep 2020 03:21:00
	System	30 Sep 2020 03:21:00

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:20:50', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'af392203-5976-44a2-ac88-10188b073591' User entered '98.5'	System	30 Sep 2020 03:21:00
	System	30 Sep 2020 03:21:00

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:20:54', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'af392203-5976-44a2-ac88-10188b073591'	System	30 Sep 2020 03:21:00
User entered 'No (N)'	System	30 Sep 2020 03:21:00



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:20:58', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'af392203-5976-44a2-ac88-10188b073591' User entered '29 Sep 2020 23:20'	System	30 Sep 2020 03:21:00
	System	30 Sep 2020 03:21:00

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 2'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:57:56', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b1fa6dde-bf71-4fe7-86ce-d2bd02f4ed2c' User entered 'Yes (Y)'	System	01 Oct 2020 02:58:08
	System	01 Oct 2020 02:58:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:01', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b1fa6dde-bf71-4fe7-86ce-d2bd02f4ed2c' User entered '97.9'	System	01 Oct 2020 02:58:08
	System	01 Oct 2020 02:58:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:04', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b1fa6dde-bf71-4fe7-86ce-d2bd02f4ed2c'	System	01 Oct 2020 02:58:08
User entered 'No (N)'	System	01 Oct 2020 02:58:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:07', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b1fa6dde-bf71-4fe7-86ce-d2bd02f4ed2c'	System	01 Oct 2020 02:58:08
User entered '30 Sep 2020 22:58'	System	01 Oct 2020 02:58:08



US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 3'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:49:45', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '143327cc-e79b-4ad6-98df-8bae62499350' User entered 'Yes (Y)'	System	02 Oct 2020 07:50:17
	System	02 Oct 2020 07:50:17

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:49:58', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '143327cc-e79b-4ad6-98df-8bae62499350' User entered '97.7'	System	02 Oct 2020 07:50:17
	System	02 Oct 2020 07:50:17

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '143327cc-e79b-4ad6-98df-8bae62499350' User entered 'No (N)'	System	02 Oct 2020 07:50:17
	System	02 Oct 2020 07:50:17

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '143327cc-e79b-4ad6-98df-8bae62499350' User entered '02 Oct 2020 03:50'	System	02 Oct 2020 07:50:17
	System	02 Oct 2020 07:50:17

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:22:08



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 4'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:00', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '874c4697-116c-4e99-8379-ae3dfae12cdc' User entered 'Yes (Y)'	System	03 Oct 2020 10:39:14
	System	03 Oct 2020 10:39:14

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:05', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '874c4697-116c-4e99-8379-ae3dfae12cdc' User entered '96.8'	System	03 Oct 2020 10:39:14
	System	03 Oct 2020 10:39:14

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:07', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '874c4697-116c-4e99-8379-ae3dfae12cdc' User entered 'No (N)'	System	03 Oct 2020 10:39:14
	System	03 Oct 2020 10:39:14

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '874c4697-116c-4e99-8379-ae3dfae12cdc' User entered '03 Oct 2020 06:39'	System	03 Oct 2020 10:39:14
	System	03 Oct 2020 10:39:14

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:22:08



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 5'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:52:57', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7c565997-b863-4aa6-9b5b-8a8f2173ce20' User entered 'Yes (Y)'	System	04 Oct 2020 12:53:22
	System	04 Oct 2020 12:53:22

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:00', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7c565997-b863-4aa6-9b5b-8a8f2173ce20' User entered '99.3'	System	04 Oct 2020 12:53:22
	System	04 Oct 2020 12:53:22

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:02', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7c565997-b863-4aa6-9b5b-8a8f2173ce20'	System	04 Oct 2020 12:53:22
User entered 'No (N)'	System	04 Oct 2020 12:53:22

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:20', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7c565997-b863-4aa6-9b5b-8a8f2173ce20' User entered '04 Oct 2020 08:53'	System	04 Oct 2020 12:53:22
	System	04 Oct 2020 12:53:22

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 6'	System	29 Sep 2020 14:22:08



US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:44', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '684d244f-3506-47a7-8cd1-bd40ee5d62c5' User entered 'Yes (Y)'	System	05 Oct 2020 09:17:54
	System	05 Oct 2020 09:17:54

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:47', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '684d244f-3506-47a7-8cd1-bd40ee5d62c5' User entered '98.3'	System	05 Oct 2020 09:17:54
	System	05 Oct 2020 09:17:54

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:50', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '684d244f-3506-47a7-8cd1-bd40ee5d62c5'	System	05 Oct 2020 09:17:54
User entered 'No (N)'	System	05 Oct 2020 09:17:54

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:52', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '684d244f-3506-47a7-8cd1-bd40ee5d62c5' User entered '05 Oct 2020 05:17'	System	05 Oct 2020 09:17:54
	System	05 Oct 2020 09:17:54

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 7'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:44', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b515bab6-66c5-4bbf-b0c3-8b606a77e0d1' User entered 'Yes (Y)'	System	06 Oct 2020 02:34:55
	System	06 Oct 2020 02:34:55



US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:48', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b515bab6-66c5-4bbf-b0c3-8b606a77e0d1' User entered '97.8'	System	06 Oct 2020 02:34:55
	System	06 Oct 2020 02:34:55

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:50', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b515bab6-66c5-4bbf-b0c3-8b606a77e0d1'	System	06 Oct 2020 02:34:55
User entered 'No (N)'	System	06 Oct 2020 02:34:55

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:52', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b515bab6-66c5-4bbf-b0c3-8b606a77e0d1' User entered '05 Oct 2020 22:34'	System	06 Oct 2020 02:34:55
	System	06 Oct 2020 02:34:55

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:53', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered 'None (1)'	System	29 Sep 2020 14:51:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:56', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered 'No (N)'	System	29 Sep 2020 14:51:08



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:59', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered 'No (N)'	System	29 Sep 2020 14:51:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:02', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered 'None (1)'	System	29 Sep 2020 14:51:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:06', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318' User entered '29 Sep 2020 10:51'	System	29 Sep 2020 14:51:08
	System	29 Sep 2020 14:51:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 10:35'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 13:05'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:06', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337'	System	30 Sep 2020 03:21:22
User entered 'None (1)'	System	30 Sep 2020 03:21:22

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:09', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337' User entered 'No (N)'	System	30 Sep 2020 03:21:22
	System	30 Sep 2020 03:21:22



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337'	System	30 Sep 2020 03:21:22
User entered 'No (N)'	System	30 Sep 2020 03:21:22

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337'	System	30 Sep 2020 03:21:22
User entered 'None (1)'	System	30 Sep 2020 03:21:22

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:19', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337' User entered '29 Sep 2020 23:21'	System	30 Sep 2020 03:21:22
	System	30 Sep 2020 03:21:22

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 2'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:12', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0'	System	01 Oct 2020 02:58:25
User entered 'None (1)'	System	01 Oct 2020 02:58:25

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:14', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0' User entered 'No (N)'	System	01 Oct 2020 02:58:25
	System	01 Oct 2020 02:58:25



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:17', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0' User entered 'No (N)'	System	01 Oct 2020 02:58:25
	System	01 Oct 2020 02:58:25

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:21', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0'	System	01 Oct 2020 02:58:25
User entered 'None (1)'	System	01 Oct 2020 02:58:25

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0' User entered '30 Sep 2020 22:58'	System	01 Oct 2020 02:58:25
	System	01 Oct 2020 02:58:25

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 3'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b' User entered 'None (1)'	System	02 Oct 2020 07:50:27
	System	02 Oct 2020 07:50:27

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:19', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b' User entered 'No (N)'	System	02 Oct 2020 07:50:27
	System	02 Oct 2020 07:50:27



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:21', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcb7-8ac9-4e0d-8274-8ce8d1bd314b' User entered 'No (N)'	System	02 Oct 2020 07:50:27
	System	02 Oct 2020 07:50:27

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b' User entered 'None (1)'	System	02 Oct 2020 07:50:27
	System	02 Oct 2020 07:50:27

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:25', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b' User entered '02 Oct 2020 03:50'	System	02 Oct 2020 07:50:27
	System	02 Oct 2020 07:50:27

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 4'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d' User entered 'None (1)'	System	03 Oct 2020 10:39:26
	System	03 Oct 2020 10:39:26

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d' User entered 'No (N)'	System	03 Oct 2020 10:39:26
	System	03 Oct 2020 10:39:26



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:18', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d' User entered 'No (N)'	System	03 Oct 2020 10:39:26
	System	03 Oct 2020 10:39:26

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:20', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d' User entered 'None (1)'	System	03 Oct 2020 10:39:26
	System	03 Oct 2020 10:39:26

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:22', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d' User entered '03 Oct 2020 06:39'	System	03 Oct 2020 10:39:26
	System	03 Oct 2020 10:39:26

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 5'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:24', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered 'None (1)'	System	04 Oct 2020 12:53:38

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:26', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered 'No (N)'	System	04 Oct 2020 12:53:38



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:28', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered 'No (N)'	System	04 Oct 2020 12:53:38

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered 'None (1)'	System	04 Oct 2020 12:53:38

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:32', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered '04 Oct 2020 08:53'	System	04 Oct 2020 12:53:38

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 6'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:54', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac'	System	05 Oct 2020 09:18:08
User entered 'None (1)'	System	05 Oct 2020 09:18:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:57', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac' User entered 'No (N)'	System	05 Oct 2020 09:18:08
	System	05 Oct 2020 09:18:08



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:59', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac' User entered 'No (N)'	System	05 Oct 2020 09:18:08
	System	05 Oct 2020 09:18:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:02', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac'	System	05 Oct 2020 09:18:08
User entered 'None (1)'	System	05 Oct 2020 09:18:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:04', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac' User entered '05 Oct 2020 05:18'	System	05 Oct 2020 09:18:08
	System	05 Oct 2020 09:18:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 7'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:56', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a' User entered 'None (1)'	System	06 Oct 2020 02:35:09
	System	06 Oct 2020 02:35:09

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:58', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a' User entered 'No (N)'	System	06 Oct 2020 02:35:09
	System	06 Oct 2020 02:35:09



US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:00', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a' User entered 'No (N)'	System	06 Oct 2020 02:35:09
	System	06 Oct 2020 02:35:09

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:02', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a' User entered 'None (1)'	System	06 Oct 2020 02:35:09
	System	06 Oct 2020 02:35:09

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:04', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a' User entered '05 Oct 2020 22:35'	System	06 Oct 2020 02:35:09
	System	06 Oct 2020 02:35:09

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:17', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160' User entered 'None (0)'	System	29 Sep 2020 14:51:37
	System	29 Sep 2020 14:51:37

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:20', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160' User entered 'None (0)'	System	29 Sep 2020 14:51:37
	System	29 Sep 2020 14:51:37



US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:22', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160' User entered 'None (0)'	System	29 Sep 2020 14:51:37
	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:24', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160' User entered 'None (0)'	System	29 Sep 2020 14:51:37
	System	29 Sep 2020 14:51:37

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160' User entered 'None (0)'	System	29 Sep 2020 14:51:37
	System	29 Sep 2020 14:51:37

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160' User entered 'None (0)'	System	29 Sep 2020 14:51:37
	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160' User entered 'No (N)'	System	29 Sep 2020 14:51:37
	System	29 Sep 2020 14:51:37

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:34', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160' User entered '29 Sep 2020 10:51'	System	29 Sep 2020 14:51:37
	System	29 Sep 2020 14:51:37

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 10:35'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 13:05'	System	29 Sep 2020 14:22:08



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe' User entered 'None (0)'	System	30 Sep 2020 03:21:41
	System	30 Sep 2020 03:21:41

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:25', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe' User entered 'None (0)'	System	30 Sep 2020 03:21:41
	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe' User entered 'None (0)'	System	30 Sep 2020 03:21:41
	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe' User entered 'None (0)'	System	30 Sep 2020 03:21:41
	System	30 Sep 2020 03:21:41

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe' User entered 'None (0)'	System	30 Sep 2020 03:21:41
	System	30 Sep 2020 03:21:41

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:33', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe' User entered 'None (0)'	System	30 Sep 2020 03:21:41
	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:37', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe' User entered 'No (N)'	System	30 Sep 2020 03:21:41
	System	30 Sep 2020 03:21:41



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:39', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe' User entered '29 Sep 2020 23:21'	System	30 Sep 2020 03:21:41
	System	30 Sep 2020 03:21:41

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 2'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed' User entered 'None (0)'	System	01 Oct 2020 02:58:45
	System	01 Oct 2020 02:58:45

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed' User entered 'None (0)'	System	01 Oct 2020 02:58:45
	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed' User entered 'None (0)'	System	01 Oct 2020 02:58:45
	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:33', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed' User entered 'None (0)'	System	01 Oct 2020 02:58:45
	System	01 Oct 2020 02:58:45



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:35', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed' User entered 'None (0)'	System	01 Oct 2020 02:58:45
	System	01 Oct 2020 02:58:45

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:37', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed' User entered 'None (0)'	System	01 Oct 2020 02:58:45
	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:39', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed' User entered 'No (N)'	System	01 Oct 2020 02:58:45
	System	01 Oct 2020 02:58:45

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:41', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed' User entered '30 Sep 2020 22:58'	System	01 Oct 2020 02:58:45
	System	01 Oct 2020 02:58:45

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 3'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered 'None (0)'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered 'None (0)'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered 'None (0)'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:33', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered 'None (0)'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:34', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered 'None (0)'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:36', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered 'None (0)'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:38', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered 'No (N)'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:40', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered '02 Oct 2020 03:50'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:22:08



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 4'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:25', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered 'None (0)'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:26', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered 'None (0)'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:28', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered 'None (0)'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:30', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered 'None (0)'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered 'None (0)'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:32', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered 'None (0)'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38



US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:34', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered 'No (N)'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:36', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered '03 Oct 2020 06:39'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 5'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:35', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b' User entered 'None (0)'	System	04 Oct 2020 12:53:49
	System	04 Oct 2020 12:53:49

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:37', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b' User entered 'None (0)'	System	04 Oct 2020 12:53:49
	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:38', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b' User entered 'None (0)'	System	04 Oct 2020 12:53:49
	System	04 Oct 2020 12:53:49



US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:39', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b' User entered 'None (0)'	System	04 Oct 2020 12:53:49
	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:41', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b' User entered 'None (0)'	System	04 Oct 2020 12:53:49
	System	04 Oct 2020 12:53:49

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:42', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b' User entered 'None (0)'	System	04 Oct 2020 12:53:49
	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:43', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b' User entered 'No (N)'	System	04 Oct 2020 12:53:49
	System	04 Oct 2020 12:53:49

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:45', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b' User entered '04 Oct 2020 08:53'	System	04 Oct 2020 12:53:49
	System	04 Oct 2020 12:53:49

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 6'	System	29 Sep 2020 14:22:08



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:06', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:08', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:09', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:12', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:14', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'No (N)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered '05 Oct 2020 05:18'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 7'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97' User entered 'None (0)'	System	06 Oct 2020 02:35:25
	System	06 Oct 2020 02:35:25

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:12', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97' User entered 'None (0)'	System	06 Oct 2020 02:35:25
	System	06 Oct 2020 02:35:25

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97' User entered 'None (0)'	System	06 Oct 2020 02:35:25
	System	06 Oct 2020 02:35:25

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:15', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97' User entered 'None (0)'	System	06 Oct 2020 02:35:25
	System	06 Oct 2020 02:35:25

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:17', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97' User entered 'None (0)'	System	06 Oct 2020 02:35:25
	System	06 Oct 2020 02:35:25



**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:19', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97' User entered 'None (0)'	System	06 Oct 2020 02:35:25
	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:21', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered 'No (N)'	System	06 Oct 2020 02:35:25

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97' User entered '05 Oct 2020 22:35'	System	06 Oct 2020 02:35:25
	System	06 Oct 2020 02:35:25

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:59:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:08:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

**US3602111**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:58:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 12:47:45

**US3602111**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:58:16
User entered '6 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 12:47:45

**US3602111**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:58:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	09 Oct 2020 12:47:45



**US3602111**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:58:16
User entered '8:38 pm and 9:10 pm - Called twice without success. Voice mailbox is full and was unable to leave a message.'	(b) (4), (b) (6)	09 Oct 2020 12:47:45

**US3602111**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 12:47:50

**US3602111**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User entered 'I'	System	09 Oct 2020 12:47:50

**US3602111**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:25:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:23:28

**US3602111**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:25:06
User entered '13 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 23:23:28

**US3602111**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:25:06
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Oct 2020 23:23:28

US3602111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:09:24
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:09:24
User entered 'CALled subject ON 10/13 at 21:09h for SCD15, no response, left VM to call back. Called subject on 10/14 at 11:00h, NO RESPONSE, left VM to call back. Subject did not call back, contact not made.' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:09:24
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:25:06
User entered 'Calls were made on 10/13 and 10/14 no response from subject.'	(b) (4), (b) (6)	28 Oct 2020 23:23:28

**US3602111**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:36:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:23:31



**US3602111**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:14:26
User entered 'I'	System	28 Oct 2020 23:23:31

**US3602111**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:35:44

**US3602111**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:11
User entered '20 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 23:35:44

US3602111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:21:17
User closed query 'Per progress notes, contact was made on 10/22/20. Please confirm and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 20:21:15
Query 'Per progress notes, contact was made on 10/22/20. Please confirm and update data accordingly.' answered with 'Contact was made on 10/20/2020, that date has 2 notes I must've missed this one.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 20:15:46
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:15:24
User opened query 'Per progress notes, contact was made on 10/22/20. Please confirm and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 19:41:06
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Oct 2020 23:35:44

**US3602111**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:21:19
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:15:24
User entered empty; reason for change New Information	(b) (4), (b) (6)	21 Dec 2020 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:41:13
User entered 'Left voicemail for subject to call back'	(b) (4), (b) (6)	28 Oct 2020 23:35:44

**US3602111**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:28
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 16:40:58
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:38:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:35:49

**US3602111**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User entered '1'	System	30 Nov 2020 16:40:58
User entered empty.	System	09 Nov 2020 16:38:35
User entered '1'	System	28 Oct 2020 23:35:49

**US3602111**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:07:24
Comment added 'Subject was in the Convalescent period during this time, COVID-19 Impact form was filled out.'	(b) (4), (b) (6)	30 Nov 2020 20:41:57
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 20:36:18



**US3602111**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:07:24
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:36:18

**US3602111**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:07:24
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:36:18

**US3602111**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered 'VISIT2'	System	30 Nov 2020 20:36:18

**US3602111**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:07:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:42:08

**US3602111**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:10
User entered '1'	System	30 Nov 2020 16:42:08

**US3602111**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:07:55
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 16:42:15

**US3602111**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:07:55
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:15

**US3602111**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:07:55
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:15



US3602111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:12:18
User entered 'Subject was in convalescent period' reason for change: New Information	(b) (4), (b) (6)	28 Jan 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:07:55
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:15

**US3602111**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:08:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:42:19

**US3602111**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'I'	System	30 Nov 2020 16:42:19

**US3602111**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:11:09
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 16:42:27

**US3602111**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:11:09
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:27

**US3602111**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:11:09
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:27

US3602111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:12:33
User entered 'Subject was in convalescent period' reason for change: New Information	(b) (4), (b) (6)	28 Jan 2021 17:12:33
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:11:09
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:27

**US3602111**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:11:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:42:31



**US3602111**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'I'	System	30 Nov 2020 16:42:31

**US3602111**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:45:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 16:42:38

**US3602111**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:45:25
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:38

**US3602111**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:45:25
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:38

US3602111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:12:46
User entered 'Subject was in convalescent period' reason for change: New Information	(b) (4), (b) (6)	28 Jan 2021 17:12:46
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 02:45:25
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:42:38

**US3602111**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:45:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:42:43

**US3602111**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'I'	System	30 Nov 2020 16:42:43

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:54:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:42:54



**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:54:14
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:42:54

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:54:14
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Nov 2020 16:42:54

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'VISIT3'	System	30 Nov 2020 16:42:54

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered '08:20'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered '30 Nov 2020 08:20'	System	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered '97.2' F	(b) (4), (b) (6)	30 Nov 2020 16:43:42



**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered 'Other (Other)'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered 'Temporal'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered '66'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'bpm'	System	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered '16'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'breaths/min'	System	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:55:24
User entered '115'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'mmHg'	System	30 Nov 2020 16:43:42



**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4)	22 Dec 2020 02:55:24
User entered '76'	(b) (4), (b) (6)	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'mmHg'	System	30 Nov 2020 16:43:42

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16

US3602111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:12:01
User closed query 'Progress notes states "Symptoms directed only" Please confirm if PE was completed and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 19:04:25
Query 'Progress notes states "Symptoms directed only" Please confirm if PE was completed and update accordingly.' answered with 'a physical exam was administered in which the provider addressed the symptoms only. confirming the exam was completed' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:22:16
User opened query 'Progress notes states "Symptoms directed only" Please confirm if PE was completed and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 02:58:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:43:50

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:59:25**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:58:23
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:43:50

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:58:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:44:03

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:58:45
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:44:03



**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:58:45
User entered '08:20'	(b) (4), (b) (6)	30 Nov 2020 16:44:03

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered '30 Nov 2020 08:20'	System	30 Nov 2020 16:44:03

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 02:58:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:44:07

**US3602111**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:28:16
User entered 'I'	System	30 Nov 2020 16:44:07

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-11-30T08:33:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '149573a2-69b6-421d-9b44-f3196569c599'	System	30 Nov 2020 13:33:28
User entered 'No (N)'	System	30 Nov 2020 13:33:28

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-11-30T08:33:18', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '149573a2-69b6-421d-9b44-f3196569c599'	System	30 Nov 2020 13:33:28
User entered 'No (N)'	System	30 Nov 2020 13:33:28

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-11-30T08:33:24', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '149573a2-69b6-421d-9b44-f3196569c599' User entered '30 Nov 2020 08:33:24'	System	30 Nov 2020 13:33:28
	System	30 Nov 2020 13:33:28



**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-05T12:00:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '2b0a0512-1a39-4f3d-8c38-c7cb0ab6fa6f'	System	05 Dec 2020 17:00:27
User entered 'No (N)'	System	05 Dec 2020 17:00:27

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-05T12:00:19', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '2b0a0512-1a39-4f3d-8c38-c7cb0ab6fa6f' User entered 'No (N)'	System	05 Dec 2020 17:00:27
	System	05 Dec 2020 17:00:27

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-05T12:00:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '2b0a0512-1a39-4f3d-8c38-c7cb0ab6fa6f' User entered '05 Dec 2020 12:00:23'	System	05 Dec 2020 17:00:27
	System	05 Dec 2020 17:00:27

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 11:07:21



**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-10T07:06:42', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'd9dda38-e15e-4643-9d8d-7a1133be45cc'	System	10 Dec 2020 12:06:50
User entered 'No (N)'	System	10 Dec 2020 12:06:50

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-10T07:06:45', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'd9ddda38-e15e-4643-9d8d-7a1133be45cc'	System	10 Dec 2020 12:06:50
User entered 'No (N)'	System	10 Dec 2020 12:06:50

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-10T07:06:48', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'd9ddda38-e15e-4643-9d8d-7a1133be45cc' User entered '10 Dec 2020 07:06:48'	System	10 Dec 2020 12:06:50
	System	10 Dec 2020 12:06:50

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-17T00:01:44', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '2eb50a2b-2381-49dd-9707-cd87c0b9eced' User entered 'No (N)'	System	17 Dec 2020 05:02:06
	System	17 Dec 2020 05:02:06



US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-17T00:01:47', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '2eb50a2b-2381-49dd-9707-cd87c0b9eced' User entered 'No (N)'	System	17 Dec 2020 05:02:06
	System	17 Dec 2020 05:02:06

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-17T00:01:49', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '2eb50a2b-2381-49dd-9707-cd87c0b9eced' User entered '17 Dec 2020 00:01:49'	System	17 Dec 2020 05:02:06
	System	17 Dec 2020 05:02:06

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-24T00:56:44', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'fa5b4199-8500-456f-a404-1378e3077b27'	System	24 Dec 2020 05:56:55
User entered 'No (N)'	System	24 Dec 2020 05:56:55

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-24T00:56:47', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'fa5b4199-8500-456f-a404-1378e3077b27'	System	24 Dec 2020 05:56:55
User entered 'No (N)'	System	24 Dec 2020 05:56:55

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-24T00:56:51', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'fa5b4199-8500-456f-a404-1378e3077b27' User entered '24 Dec 2020 00:56:51'	System	24 Dec 2020 05:56:55
	System	24 Dec 2020 05:56:55



**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-31T00:01:17', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'ffebe1da-fe44-4efb-8cc7-7fdbd77964e5' User entered 'No (N)'	System	31 Dec 2020 05:01:31
	System	31 Dec 2020 05:01:31

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-31T00:01:19', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'ffebe1da-fe44-4efb-8cc7-7fdbd77964e5' User entered 'No (N)'	System	31 Dec 2020 05:01:31
	System	31 Dec 2020 05:01:31

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-12-31T00:01:22', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'ffebe1da-fe44-4efb-8cc7-7fdbd77964e5' User entered '31 Dec 2020 00:01:22'	System	31 Dec 2020 05:01:31
	System	31 Dec 2020 05:01:31

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 11:07:21



**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-07T00:02:17', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '93d36c17-97e9-4ee1-94b6-354711a0a6c2' User entered 'No (N)'	System	07 Jan 2021 05:02:47
	System	07 Jan 2021 05:02:47

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-07T00:02:20', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '93d36c17-97e9-4ee1-94b6-354711a0a6c2' User entered 'No (N)'	System	07 Jan 2021 05:02:47
	System	07 Jan 2021 05:02:47

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-07T00:02:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '93d36c17-97e9-4ee1-94b6-354711a0a6c2' User entered '07 Jan 2021 00:02:23'	System	07 Jan 2021 05:02:47
	System	07 Jan 2021 05:02:47

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-14T00:01:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '58c37774-60c9-4b05-aa59-0a6517cedd6f' User entered 'No (N)'	System	14 Jan 2021 05:01:50
	System	14 Jan 2021 05:01:50



US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-14T00:01:35', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '58c37774-60c9-4b05-aa59-0a6517cedd6f' User entered 'No (N)'	System	14 Jan 2021 05:01:50
	System	14 Jan 2021 05:01:50

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-14T00:01:37', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '58c37774-60c9-4b05-aa59-0a6517cedd6f' User entered '14 Jan 2021 00:01:37'	System	14 Jan 2021 05:01:50
	System	14 Jan 2021 05:01:50

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-21T01:13:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3855a29f-7507-4f93-83e4-1d597bd67a37' User entered 'No (N)'	System	21 Jan 2021 06:13:18
	System	21 Jan 2021 06:13:18

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-21T01:13:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3855a29f-7507-4f93-83e4-1d597bd67a37'	System	21 Jan 2021 06:13:18
User entered 'No (N)'	System	21 Jan 2021 06:13:18

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-21T01:13:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3855a29f-7507-4f93-83e4-1d597bd67a37'	System	21 Jan 2021 06:13:18
User entered '21 Jan 2021 01:13:16'	System	21 Jan 2021 06:13:18



**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-28T00:33:45', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '59f4b295-5b45-417d-a2d5-5ce042b85d52'	System	28 Jan 2021 05:33:52
User entered 'No (N)'	System	28 Jan 2021 05:33:52

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-28T00:33:48', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '59f4b295-5b45-417d-a2d5-5ce042b85d52'	System	28 Jan 2021 05:33:52
User entered 'No (N)'	System	28 Jan 2021 05:33:52

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-01-28T00:33:50', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '59f4b295-5b45-417d-a2d5-5ce042b85d52' User entered '28 Jan 2021 00:33:50'	System	28 Jan 2021 05:33:52
	System	28 Jan 2021 05:33:52

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 11:07:21



**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-02-04T00:03:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '10e30899-7b09-4a49-9859-23235b5c2d1e' User entered 'No (N)'	System	04 Feb 2021 05:03:38
	System	04 Feb 2021 05:03:38

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:25

Have you been exposed to someone with 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)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-02-04T00:03:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '10e30899-7b09-4a49-9859-23235b5c2d1e' User entered 'No (N)'	System	04 Feb 2021 05:03:38
	System	04 Feb 2021 05:03:38

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2021-02-04T00:03:32', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '10e30899-7b09-4a49-9859-23235b5c2d1e' User entered '04 Feb 2021 00:03:32'	System	04 Feb 2021 05:03:38
	System	04 Feb 2021 05:03:38

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 11:07:21

**US3602111**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 11:07:21

**US3602111**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 15:12:52

**US3602111**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:50
User entered '24 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 16:03:14
User entered '22 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 15:12:52



**US3602111**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:50
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 16:03:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	23 Dec 2020 15:12:52

US3602111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:13:55
User entered 'SUBJECT returned CALL ON 12/24' reason for change: New Information	(b) (4), (b) (6)	05 Jan 2021 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:50
User entered 'Subject called on 12/24' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 16:03:14
User entered 'Subject unreachable at any documented contact numbers will try to initiate a line of contact'	(b) (4), (b) (6)	23 Dec 2020 15:12:52

**US3602111**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 15:09:52

**US3602111**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:03
User entered 'I'	System	23 Dec 2020 15:09:52

**US3602111**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:20
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 04:50:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 16:52:43

**US3602111**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:20
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 04:50:08
User entered '27 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 16:52:43

**US3602111**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:20
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 04:50:08
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Jan 2021 16:52:43

**US3602111**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:20
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 04:50:08
User entered 'LVMTCB --1/25 ( 5pm), 1/26 (7:05pm) and 1/27 (4pm)'	(b) (4), (b) (6)	28 Jan 2021 16:52:43



**US3602111**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:20
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 04:50:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 16:52:50

**US3602111**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:20
User entered 'I'	System	28 Jan 2021 16:52:50

US3602111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4)	
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:12:45
	(b) (4), (b) (6)	
Query 'Data is required. Please complete.' answered with 'Subject withdrew consent on 06-Feb-2021.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 14:24:51
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 14:24:29
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:24:29
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:24:29
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	17 Feb 2021 15:10:59

**US3602111**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:10:59

**US3602111**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:10:59

**US3602111**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:10:59

US3602111

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4)	
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 06:12:51
	(b) (4), (b) (6)	
Query 'Data is required. Please complete.' answered with 'Subject withdrew consent on 06-Feb-2021.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 14:25:06
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 14:25:00
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:25:00
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:25:00
	(b) (4)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	17 Feb 2021 15:11:10
	(b) (4), (b) (6)	

**US3602111**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered empty.	System	17 Feb 2021 15:11:10



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:25

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:20:39
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:11:15
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 23:38:00

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:25

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
Comment added 'Time of encounter was 14:29. updated the crf'.	(b) (4), (b) (6)	10 Nov 2020 21:22:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:22:19
User entered '14:29' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:21:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 16:42:47
Query 'Data is required. Please complete.' answered with 'no time noted' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 23:38:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:38:00
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 23:38:00

**US3602111**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:59:25**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '26 Oct 2020 14:29'	System	10 Nov 2020 21:21:19
User entered empty.	System	28 Oct 2020 23:38:00

**US3602111**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:59:25**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:22:30
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	28 Oct 2020 23:38:00

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:25

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:22:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:38:00

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 1 (Day 1)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 3 (Day 3)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 1 (Day 1)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 20:02:13
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User closed query 'Per source, patient presenting with fever, chills, fatigue and positive COVID exposure at work on 23-Oct-2020. Please confirm if subject's symptoms started on 23-Oct-2020 and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 20:43:26
Query 'Per source, patient presenting with fever, chills, fatigue and positive COVID exposure at work on 23-Oct-2020. Please confirm if subject's symptoms started on 23-Oct-2020 and update data accordingly.' answered with 'Subject was exposed to a COVID+ person on 10/23 but on 10/24 started to experience symptoms. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:52:08
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:18:47
User opened query 'Per source, patient presenting with fever, chills, fatigue and positive COVID exposure at work on 23-Oct-2020. Please confirm if subject's symptoms started on 23-Oct-2020 and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:18:44
User entered '24 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '26 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:38:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 19:38:47
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:30:59
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:30:59



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:20:56
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '94' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	10 Nov 2020 23:20:56
User entered empty.	System	10 Nov 2020 23:13:48
User entered '%'	System	05 Nov 2020 19:38:47
User entered empty.	System	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered '99.9' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:40:59
User entered '101' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 23:20:56
User entered '99.9' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:20:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 23:19:36
User entered '99.9' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '98.2' F reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User closed query 'Per progress notes, Cough started 25Oct2020. Please verify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:22:10
Query 'Per progress notes, Cough started 25Oct2020. Please verify data and update accordingly.' answered with 'update' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 20:21:04
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:20:56
User opened query 'Per progress notes, Cough started 25Oct2020. Please verify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 20:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:15:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:16
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:19
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:22
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:24
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
	(b) (4), (b) (6)	
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
	(b) (4), (b) (6)	
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
	(b) (4), (b) (6)	
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59
	(b) (4), (b) (6)	

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered '25 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '29 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
	(b) (4), (b) (6)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '99'	(b) (4), (b) (6)	05 Nov 2020 20:02:13
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	10 Nov 2020 23:26:21
User entered empty.	System	10 Nov 2020 23:13:48
User entered '%'	System	05 Nov 2020 20:02:13



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered '99.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:40:59
User entered '101' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '98.7' F	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '30 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User closed query "The assessment was done. Should this box be checked on this page and subsequent pages?" (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 15:15:11
Query "The assessment was done. Should this box be checked on this page and subsequent pages?" answered with 'per your instructions if the subject reported symptoms lasting from start date to visit date use that information to complete the symptom log. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:05:25
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:22:25
User opened query "The assessment was done. Should this box be checked on this page and subsequent pages?" (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:49:05
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:48:03
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 15:18:47
User closed query 'Progress notes on 26Oct2020 has SpO2 100%. Please confirm and update data accordingly. ' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 15:18:44
Query 'Progress notes on 26Oct2020 has SpO2 100%. Please confirm and update data accordingly. ' answered with 'subject was not seen by provider until 10/27 where the subject received the SpO2 reader. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:08
User opened query 'Progress notes on 26Oct2020 has SpO2 100%. Please confirm and update data accordingly. ' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 21:44:40
Query 'Per progress notes on 27Oct2020 has 97-100% spo2. Please confirm and update data accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 21:43:30
User opened query 'Per progress notes on 27Oct2020 has 97-100% spo2. Please confirm and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 21:39:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:37:06
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered '101' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:40:59
User entered '99.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '98' F	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 15:30:15
User closed query 'Per progress notes, event stopped on 26Oct2020 at 6:00 am. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 15:30:12
Query 'Per progress notes, event stopped on 26Oct2020 at 6:00 am. Please confirm data and update accordingly.' answered with 'per note from BB on 10/27 states stop date was the morning of 10/27' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:08:07
User opened query 'Per progress notes, event stopped on 26Oct2020 at 6:00 am. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:06:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:03:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:58:10
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 21:58:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:33
User closed query 'Per progress notes on 26Oct2020, subject tested positive for sore throat. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 17:10:00
Query 'Per progress notes on 26Oct2020, subject tested positive for sore throat. Please confirm data and update accordingly.' answered with 'subject only reports fever, chills, fatigue, and cough in 10/26/2020 notes' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:11:09
User opened query 'Per progress notes on 26Oct2020, subject tested positive for sore throat. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 21:59:35
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 21:56:45
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '31 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:22:20
Query "The assessment was done. Should this box be checked on this page and subsequent pages?" canceled (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:55:16
User opened query "The assessment was done. Should this box be checked on this page and subsequent pages?" (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:50:23
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:49:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '98.4' F	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 15:32:23
User closed query 'Per progress notes, event stopped on 27Oct2020 at 4:00 pm. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 15:32:21
Query 'Per progress notes, event stopped on 27Oct2020 at 4:00 pm. Please confirm data and update accordingly.' answered with 'On 10/27 subject was still having chills. please note for 10/28 no chills reported' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:13:22
User opened query 'Per progress notes, event stopped on 27Oct2020 at 4:00 pm. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 21:53:34
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 21:52:38
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33



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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User closed query 'Per progress notes, event stopped on 27Oct2020 at 10:00 pm. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 17:13:50
Query 'Per progress notes, event stopped on 27Oct2020 at 10:00 pm. Please confirm data and update accordingly.' answered with '"Confirming event was still present on 10/27/2020 until 10pm at which symptom resolved' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:16:41
User opened query 'Per progress notes, event stopped on 27Oct2020 at 10:00 pm. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 21:55:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 5 (Day 5)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 7 (Day 7)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 5 (Day 5)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered '28 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '30 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '28 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:22:15
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:55:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered '0' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 20:13:24



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:50:51
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	10 Nov 2020 23:13:48
User entered empty.	System	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered '98' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:50:51
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:52:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:59:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:52:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:52:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered '1 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:22:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:57:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:37:45
Query 'CRA unable to verify temperature. Please confirm data and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:37:40
User opened query 'CRA unable to verify temperature. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:33:19
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:20:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	05 Nov 2020 20:14:39



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:37:47
Query 'CRA unable to verify temperature. Please confirm data and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:37:43
User opened query 'CRA unable to verify temperature. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:20:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:19:29
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered '98.7' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.4' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered '98' F	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:52:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered '30 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '1 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '2 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:22:06
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:59:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered '0' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered '100' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	10 Nov 2020 22:12:14
User entered empty.	System	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:09:29
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:08:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	05 Nov 2020 20:15:51



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered '31 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '2 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '3 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:22:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:00:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 20:15:51
	(b) (4), (b) (6)	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	11 Nov 2020 15:38:33
User entered empty.	System	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered '98.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:05:44
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:21:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:21:38
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered '1 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '3 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:21:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered '0' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered '1' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:16:45



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered '100' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '99'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	10 Nov 2020 23:26:21
User entered empty.	System	10 Nov 2020 22:12:14
User entered '%'	System	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.2' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '97.8' F	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:12
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:21:38
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	04 Mar 2021 17:21:38
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered '2 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '4 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '5 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:21:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:11:27
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered '99' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '99' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '100' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	11 Nov 2020 17:42:34
User entered empty.	System	11 Nov 2020 15:38:33
User entered '%'	System	09 Nov 2020 16:24:40
User entered empty.	System	09 Nov 2020 16:20:39



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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered '97' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '97.8' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39



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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
	(b) (4), (b) (6)	
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
	(b) (4), (b) (6)	
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
	(b) (4), (b) (6)	
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39
	(b) (4), (b) (6)	

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39



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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered '3 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '5 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '6 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Form: Symptom Log (11)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:21:45
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:19:59
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered '100' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '99' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	09 Nov 2020 16:24:40
User entered empty.	System	09 Nov 2020 16:20:51

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:40
User closed query 'Per progress notes, temperature is 98.8. Please verify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 16:20:22
Query 'Per progress notes, temperature is 98.8. Please verify data and update accordingly.' answered with 'note from BB states "8 11/3 1015a 98.2 100 no symptoms " follows the format "Day date Time of contact Highest temp of the day: Lowest pulse ox % symptoms" respectively' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:20:21
User opened query 'Per progress notes, temperature is 98.8. Please verify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 23:21:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:20:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered '98.2' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '97.4' F reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered '4 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '6 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered '7 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:21:36
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:21:29
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered '100'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	09 Nov 2020 16:24:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered '98.5' F	(b) (4), (b) (6)	09 Nov 2020 16:24:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 13 (Day 13)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 14 (Day 14)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 13 (Day 13)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered '5 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:39:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 21:39:34
User entered '7 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:24:44
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:24:44



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered '100' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	System	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.5' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 14 (Day 14)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered '6 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '24 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	10 Nov 2020 23:20:56



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '101' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered '99.9' F	(b) (4), (b) (6)	10 Nov 2020 23:20:56

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:20:28
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:31:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:31:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 15 (Day 15)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 03:30:37
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 03:30:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered '7 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '25 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:49:06
User entered '101' F	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:26:21



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:07:07
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:31:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:31:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 14:59:26
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 14:59:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 16 (Day 16)' reason for change:	(b) (4), (b) (6)	22 Dec 2020 17:20:59
Data Entry Error		
User entered 'Day 19 (Day 19)'	(b) (4), (b) (6)	20 Nov 2020 14:18:16



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User closed query 'Day 15 was 07Nov2020 and it goes to Day 19 n 08Nov2020. Confirm if this should be Day 16 and update data accordingly.	(b) (4), (b) (6)	05 Jan 2021 16:49:43
Provide data for Day 16, Day 17, and Day 18, if available or provide explanation EMR.' (Site from CRA).		
Query 'Day 15 was 07Nov2020 and it goes to Day 19 n 08Nov2020. Confirm if this should be Day 16 and update data accordingly.	(b) (4), (b) (6)	22 Dec 2020 17:21:22
Provide data for Day 16, Day 17, and Day 18, if available or provide explanation EMR.' answered with 'updated for the correct corresponding date' (Site from CRA).		
User opened query 'Day 15 was 07Nov2020 and it goes to Day 19 n 08Nov2020. Confirm if this should be Day 16 and update data accordingly.	(b) (4), (b) (6)	22 Dec 2020 03:26:58
Provide data for Day 16, Day 17, and Day 18, if available or provide explanation EMR.' (Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered '8 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 14:18:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User closed query 'Per CDM: Please verify that Symptom Log Line 16 in Covid-19 Assessment 26 Oct 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.	(b) (4), (b) (6)	21 Apr 2021 15:27:57
' (Site from DM). Query 'Per CDM: Please verify that Symptom Log Line 16 in Covid-19 Assessment 26 Oct 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.	(b) (4), (b) (6)	20 Apr 2021 12:31:03
' answered with 'Data has been updated.' (Site from DM). User opened query 'Per CDM: Please verify that Symptom Log Line 16 in Covid-19 Assessment 26 Oct 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.	(b) (4), (b) (6)	20 Apr 2021 10:20:58
' (Site from DM). User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	04 Mar 2021 17:26:51
User entered empty.	System	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:15
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:29:51
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered 'Day 17 (Day 17)' reason for change:	(b) (4), (b) (6)	22 Dec 2020 17:20:59
Data Entry Error		
User entered 'Day 20 (Day 20)'	(b) (4), (b) (6)	20 Nov 2020 14:18:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:31:54
User entered '9 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:31:54
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered '09 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User closed query 'Per CDM: Please verify that Symptom Log Line 17 in Covid-19 Assessment 26 Oct 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:32:13
Query 'Per CDM: Please verify that Symptom Log Line 17 in Covid-19 Assessment 26 Oct 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Data has been updated.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 12:33:15
User opened query 'Per CDM: Please verify that Symptom Log Line 17 in Covid-19 Assessment 26 Oct 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:21:17
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 14:18:30



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
User entered '%'	System	04 Mar 2021 17:28:08
User entered empty.	System	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4), (b) (6)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:59:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
	(b) (4)	
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:59:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:16:04
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 12:32:52
	(b) (4)	
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 22:25:25
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 22:25:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:24:31
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:28:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:14:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:25

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:42:32
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

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Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:42:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

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[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:10
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 05:42:40
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 'will update accordingly' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 17:21:16
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
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	03 Nov 2020 17:19:56
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:17
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

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Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:22
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26



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Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:27
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:35
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:41
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

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Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:44
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

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**Form: COVID Diagnostic Test**

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'I'	System	03 Nov 2020 17:19:56

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Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37



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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Form: Covid-19 Severity Assessment

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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)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37



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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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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)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:18:32
User closed query 'Per CDM: Please review Evidence of Pneumonia section of this form and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 03:09:48
Query 'Per CDM: Please review Evidence of Pneumonia section of this form and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:22:11
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 15:22:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 15:22:06
User opened query 'Per CDM: Please review Evidence of Pneumonia section of this form and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 02:55:01
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:35:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37



US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:59:25

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:29:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 19:30:41

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:01
User entered '29 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:45
User entered '31 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23



**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:49
User entered '2 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:59:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:29:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:29:10
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:29:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:40:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:59:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:07:44
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:12:33
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:56:08
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:15
User entered '4 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:29:10
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:59:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:34:50
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:44
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	20 Nov 2020 21:12:44
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:07
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:52:44
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:36:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 20:36:38
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 20:36:38
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:40:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:59:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:34:50
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:44
User entered '09 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	20 Nov 2020 21:12:44
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:07
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 17:52:44
User entered '9 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 20:36:38
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23



**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:59:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:32:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:00:07
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 19:00:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:52:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 03:47:36
Query 'Data is required. Please complete.' answered with 'date has not occurred yet, will update accordingly.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:37:11
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:40:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:59:25**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:32:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:00:07
User entered '16 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 19:00:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:11
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:59:25

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:12:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Verified that shipment of Saliva sample was sent on 11/23/2020. Samples were originally sent to ViraCor due to using unscheduled visit kits. Once received by ViraCor PPD reverved the visit to the correct monitor. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:43:20
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 08:19:45
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:59:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:36:25
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:36:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:52:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 03:47:43
Query 'Data is required. Please complete.' answered with 'date has not occurred yet, will update accordingly.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:37:16
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:40:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:59:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:36:25
User entered '23 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:36:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:17
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:32:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:36:30

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:32:05
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:36:30



US3602111

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:25

[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 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:32:08
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Nov 2020 19:36:30

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'SICKD1'	System	05 Nov 2020 19:36:30

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:27
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:41:37
User closed query 'Per source, vitals time is 0802 (8:02 AM). Please confirm time of vitals and correct accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 20:41:35
Query 'Per source, vitals time is 0802 (8:02 AM). Please confirm time of vitals and correct accordingly.' answered with 'confirmed time with provider. updated' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:04:45
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:40
User entered '8:02' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 15:04:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:31
User opened query 'Per source, vitals time is 0802 (8:02 AM). Please confirm time of vitals and correct accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:36:14
User entered '12:17'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '27 Oct 2020 8:02'	System	12 Nov 2020 15:04:40
User entered '27 Oct 2020 12:17'	System	05 Nov 2020 19:39:35

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:20
User entered missing code ND - Not Done.	(b) (4), (b) (6)	05 Nov 2020 19:39:35
DataPoint set to visible.	System	05 Nov 2020 19:36:30

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:22
User entered missing code ND - Not Done.	(b) (4), (b) (6)	05 Nov 2020 19:39:35
DataPoint set to visible.	System	05 Nov 2020 19:36:30



US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:37
User entered '98.2' F	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:54
User entered 'Other (Other)'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:56
User entered 'Temporal'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:12
User entered '96'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'bpm'	System	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:13
User entered '20'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'breaths/min'	System	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:14
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 19:39:35



**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'mmHg'	System	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:16
User entered '73'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'mmHg'	System	05 Nov 2020 19:39:35

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

US3602111

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:39:45

US3602111

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:44
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:39:45

US3602111

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:59:25

[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 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:39:52



**US3602111**

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 11 Aug 2021 22:59:25**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:37:29
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:39:52

**US3602111**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:44:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:44:23
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:25

[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 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:44:23
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Nov 2020 14:33:39

**US3602111**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'SICKD28'	System	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '8:35'	(b) (4), (b) (6)	23 Nov 2020 14:34:50



US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '23 Nov 2020 8:35'	System	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '66' in	(b) (4), (b) (6)	23 Nov 2020 14:34:50
DataPoint set to visible.	System	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '164' lb	(b) (4), (b) (6)	23 Nov 2020 14:34:50
DataPoint set to visible.	System	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '97.3' F	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered 'Other (Other)'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered 'Temporal'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '58'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

**US3602111**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'bpm'	System	23 Nov 2020 14:34:50



US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '16'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'breaths/min'	System	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '114'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

**US3602111**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'mmHg'	System	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:50
User entered '69'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered 'mmHg'	System	23 Nov 2020 14:34:50

**US3602111**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:25**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05



US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 14:35:07

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:45:56
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 14:35:07

US3602111

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:59:25

[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 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:46:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 14:36:10

US3602111

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:59:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:46:20
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 14:36:10

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:59:25**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	14 Mar 2021 00:02:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:46:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:22:33

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:59:25**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:50:34
Query 'Sweating was not reported on the source. Please confirm if subject experienced sweating and update data accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:50:27
User opened query 'Sweating was not reported on the source. Please confirm if subject experienced sweating and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:47:23
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hyperhidrosis, LLT: Sweating - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:43:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:43:41
Data point term sent to Coder	System	10 Nov 2020 23:27:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
Data point term sent to Coder	System	06 Nov 2020 20:26:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hyperhidrosis, LLT: Sweating - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 17:56:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 17:56:25
Data point term sent to Coder	System	03 Nov 2020 17:40:17
User entered 'Sweating'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:50:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58



US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:50:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:50:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:50:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '26 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:09:16
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Nov 2020 16:05:14
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:14
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Nov 2020 16:05:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:03:30
User closed query 'Per source, start time is 6:00 pm. Please confirm time and enter accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:02:25
Query 'Per source, start time is 6:00 pm. Please confirm time and enter accordingly.' answered with 'update' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:59:29
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'CRA would like a start time listed since it is in the source document.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 15:59:25
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Nov 2020 15:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:57
User entered '18:00' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Nov 2020 15:55:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:52:18
User opened query 'Per source, start time is 6:00 pm. Please confirm time and enter accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:51:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:59:25**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User entered empty.	System	11 Nov 2020 16:05:14
User entered '26 Oct 2020 18:00'	System	11 Nov 2020 15:55:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	System	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:52:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:46:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:52:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:46:15
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58



US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:09:19
User closed query 'Per source, stop time is 4:00 pm. Please confirm stop time and enter accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:07:45
User closed query 'End time is present for an AE that System did not start within 24 hours after dosing. Please remove the End time.' (Site from System).		11 Nov 2020 16:05:14
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Nov 2020 16:05:14
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'CRA would like stop time since stop time can be found on source document' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 15:59:54
Query 'Per source, stop time is 4:00 pm. Please confirm stop time and enter accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:59:33
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	11 Nov 2020 15:58:04
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 15:58:04
User entered '14:00' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Nov 2020 15:58:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:08
User opened query 'Per source, stop time is 4:00 pm. Please confirm stop time and enter accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:53:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User entered empty.	System	11 Nov 2020 16:05:14
User entered '27 Oct 2020 14:00'	System	11 Nov 2020 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	System	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:53:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:59:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:53:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:53:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:53:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:53:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:53:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:55:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:55:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:55:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:55:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:55:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:55:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:55:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:46:15
User entered 'Related (RELATED)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:55:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'None (NONE)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:09:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:09:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:09:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:46:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:09:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:09:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:59:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	System	03 Nov 2020 17:39:58



**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:59:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	System	03 Nov 2020 17:39:58

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:59:25**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:01:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 18:59:49
User entered	System	06 Nov 2020 18:57:38
'USA-US079-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 18:57:38

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:13:31
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:38:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:38:56
Data point term sent to Coder	System	23 Nov 2020 14:38:01
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	23 Nov 2020 14:37:47
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 14:37:47
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User entered 'SYMPTOMATIC COVID -19' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4)	23 Nov 2020 12:24:13
User closed query 'PV Query: Please update event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:29:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 21:02:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Nov 2020 21:02:02
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	19 Nov 2020 21:01:26
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 21:01:22
	(b) (4), (b) (6)	
User entered 'Symptomatic Covid-19' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Nov 2020 21:01:22
Comment added 'Per CCG pg 52, if subject tests positive document at Symptomatic Covid-19'.	(b) (4), (b) (6)	19 Nov 2020 21:00:27
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:23:02
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Nov 2020 19:23:02
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Query 'PV Query: Please update event term to COVID-19.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:07:08
Data point term sent to Coder	System	19 Nov 2020 19:06:58
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:06:43
	(b) (4), (b) (6)	
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 19:06:43
	(b) (4), (b) (6)	
User entered 'COVID-19' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User opened query 'PV Query: Please update event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:52:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
	(b) (4), (b) (6)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 19:45:35
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Nov 2020 19:45:35
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 19:44:23
User entered 'Symptomatic COVID-19'	(b) (4), (b) (6)	05 Nov 2020 19:43:43
	(b) (4), (b) (6)	

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:11:59
User closed query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 30 Oct 2020; however, symptoms were reported on 27 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:29:19
Query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 30 Oct 2020; however, symptoms were reported on 27 Oct 2020.' answered with 'subject started experiencing symptoms on 10/24/2020' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:09:00
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User entered '24 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User opened query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 30 Oct 2020; however, symptoms were reported on 27 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:51:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '30 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered empty.	System	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:12:05
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:37:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:12:47
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:12:40
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:12:08
User entered '23 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 19:22:02
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 12:47:17
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:37:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User entered '02 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered empty.	System	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43



US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43



US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
User closed query 'Per CDM: Kindly consider to complete 'Dosing discontinuation' form. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:07:07
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 03:26:07
Query 'Per CDM: Kindly consider to complete 'Dosing discontinuation' form. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:26:24
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Since subject was COVID-19 positive, the subject can no longer receive second IP. The provided reasons in Dosage withdrawn allow for a more specific reasoning than AE. ' (Site from System).	(b) (4), (b) (6)	30 Nov 2020 15:26:19
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	30 Nov 2020 15:25:06
User opened query 'Per CDM: Kindly consider to complete 'Dosing discontinuation' form. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:30:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	06 Nov 2020 20:27:16
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:48:38
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:02:22
User entered '0' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 22:02:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medication that was used for this AE. Please update or provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 12:01:04
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medication that was used for this AE. Please update or provide clarification.' answered with 'Con meds were taken for the symptoms of symptomatic covid ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:06:09
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medication that was used for this AE. Please update or provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 13:38:03
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:48:38
User closed query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:05:01
Query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.' answered with 'Subject took medication for COVID-19 Symptoms' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:27:47
User opened query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:29:04



**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:02:22
User entered '1' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 22:02:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:13:40
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 12:47:20
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:37:57
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:50:33
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:13:47
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:29:15
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'covid exposure documented' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:09:35
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User entered 'Subject was exposed to COVID+ patient on 10/23/2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:51:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '0'	System	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '1'	System	05 Nov 2020 19:43:43

**US3602111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:59:25

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:48:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Dec 2020 00:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Dec 2020 00:13:38
Data point term sent to Coder	System	22 Dec 2020 00:12:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
Data point term sent to Coder	System	22 Dec 2020 00:11:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 14:32:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 14:32:43
Data point term sent to Coder	System	29 Sep 2020 14:31:39
Data point term sent to Coder	System	29 Sep 2020 14:25:22
User entered 'Albuterol Inhaler'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered 'Asthma'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '2'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered 'puff (PUFF)' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Nov 2020 15:28:18
User entered 'Other (OTHER)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User closed query 'Per CDM: "Dose unit - Other" is recorded as "PUFFS" as there is an available option for "PUFF" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list provided in the CRF and update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 10:17:37
Query 'Per CDM: "Dose unit - Other" is recorded as "PUFFS" as there is an available option for "PUFF" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list provided in the CRF and update accordingly.'	(b) (4), (b) (6)	30 Nov 2020 15:28:28
answered with 'updated' (Site from DM).		
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	30 Nov 2020 15:28:18
User opened query 'Per CDM: "Dose unit - Other" is recorded as "PUFFS" as there is an available option for "PUFF" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list provided in the CRF and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 09:11:02
User entered 'puffs'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered 'as needed (PRN)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 14:31:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 14:31:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 14:31:27
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 14:24:57
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered 'UN UNK 1993'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered empty.	System	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered empty.	System	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered empty.	System	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 00:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 00:13:38
Data point term sent to Coder	System	22 Dec 2020 00:12:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
Data point term sent to Coder	System	22 Dec 2020 00:11:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 17:53:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 17:53:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: MINERALS NOS;VITAMINS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 14:27:39

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Sep 2020 14:27:39
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	29 Sep 2020 14:26:26
User entered 'Centrum'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'Dietary Supplement'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'l'	(b) (4), (b) (6)	29 Sep 2020 14:26:08



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'UN UNK 2018'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:26:08



**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '1'	System	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '1'	System	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '804 (804)'	System	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 00:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	22 Dec 2020 00:13:38
Data point term sent to Coder	System	22 Dec 2020 00:12:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
Data point term sent to Coder	System	22 Dec 2020 00:11:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 17:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	03 Nov 2020 17:28:23
Data point term sent to Coder	System	03 Nov 2020 17:28:00
User entered 'Ibuprofen'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'Fever'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered '1200'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'three times daily (TID)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:24:17
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 16:24:17
User entered 'tid for one day the bid until 10/26 now qday.'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:27:46



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered '24 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 20:11:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered '24 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:24:17
User entered '31 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 20:11:18
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:12:03
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:45:05
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Nov 2020 16:44:58
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:17:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '3'	System	11 Nov 2020 16:24:17
User entered empty.	System	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '1'	System	11 Nov 2020 16:24:17
User entered empty.	System	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '804 (804)'	System	11 Nov 2020 16:24:17
User entered empty.	System	03 Nov 2020 17:27:46



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 00:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 00:13:38
Data point term sent to Coder	System	22 Dec 2020 00:12:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
Data point term sent to Coder	System	22 Dec 2020 00:11:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 20:12:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 20:12:23
Data point term sent to Coder	System	05 Nov 2020 20:11:41
User entered 'Ibuprofen'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'Headache'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 23:51:10
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:50:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered '1200' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:54:57
User entered '800'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:11:01



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered '29 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:28:28
User entered '1 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:28:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:14
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:15:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered '31 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:28:28
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User closed query 'Per DM: Was this medication taken for solicited event?' is recorded as "Yes". However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 04:18:27
Query 'Per DM: Was this medication taken for solicited event?' is recorded as "Yes". However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:37:46
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Nov 2020 20:37:42
User opened query 'Per DM: Was this medication taken for solicited event?' is recorded as "Yes". However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:26:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '1'	System	05 Nov 2020 20:11:01



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '1'	System	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '804 (804)'	System	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 00:13:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 00:13:39
Data point term sent to Coder	System	22 Dec 2020 00:12:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
Data point term sent to Coder	System	22 Dec 2020 00:11:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:55:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:55:33
Data point term sent to Coder	System	11 Nov 2020 16:25:07
User entered 'ibuprofen'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
User closed query 'CRA unable to verify data for ConMed 1200 mg 2 times daily for fever. Please clarify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 04:19:37
Query 'CRA unable to verify data for ConMed 1200 mg 2 times daily for fever. Please clarify data and update accordingly.' answered with 'on note from BB on 10/27 states "Medication(s) taken: ibuprofen Indication: fever Dose (unit): 1200 mg Frequency: 3x a day for the first day and then 1200mg po bid Route: oral State Date: 24 Oct End Date or Ongoing: ongoing" So day 2 will be 10/25 and that is when the subject began taking ibuprofen 1200 bid.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:03:55
User opened query 'CRA unable to verify data for ConMed 1200 mg 2 times daily for fever. Please clarify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 00:19:01
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'fever'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
User closed query 'Per progress notes, subject too 1200 mg daily for headache from 29-31-Oct-2020. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 04:19:39
Query 'Per progress notes, subject too 1200 mg daily for headache from 29-31-Oct-2020. Please confirm data and update accordingly.' answered with 'on note from BB on 10/27 states "Medication(s) taken: ibuprofen Indication: fever Dose (unit): 1200 mg Frequency: 3x a day for the first day and then 1200mg po bid Route: oral State Date: 24 Oct End Date or Ongoing: ongoing" So day 2 will be 10/25 and that is when the subject began taking ibuprofen 1200 bid.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:04:01
User opened query 'Per progress notes, subject too 1200 mg daily for headache from 29-31-Oct-2020. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 00:21:23
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered '1200'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:17:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:24:52



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
Query 'Progress notes states 1200 mg, 3x/day. Please confirm data and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 00:16:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User opened query 'Progress notes states 1200 mg, 3x/day. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 00:09:17
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:08:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 23:51:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered '25 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:16:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:17:58
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 19:05:03
User entered '28 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 19:05:03
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered '26 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 16:24:52



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:59:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '2'	System	11 Nov 2020 16:24:52

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:59:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '1'	System	11 Nov 2020 16:24:52

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:59:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '804 (804)'	System	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:25
User closed query 'Spelling "Ibuprofen"' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 04:20:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 16:59:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 16:59:31
Data point term sent to Coder	System	22 Dec 2020 16:57:47
Query 'Spelling "Ibuprofen"' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 16:57:21
Coding entries removed.	(b) (4), (b) (6)	22 Dec 2020 16:57:16
User entered 'IBUPROFEN' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Dec 2020 16:57:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 00:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 00:13:38
Data point term sent to Coder	System	22 Dec 2020 00:12:45
User opened query 'Spelling "Ibuprofen"' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 00:12:26
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:11:56

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
Data point term sent to Coder	System	22 Dec 2020 00:11:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
Data point term sent to Coder	System	11 Nov 2020 16:30:14
User entered 'Ipuprofen'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 11:02:55
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	28 Jan 2021 16:49:10
' answered with 'this indication is recorded in symptom log' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	28 Jan 2021 03:05:36
' (Site from DM).		
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'Headache'	(b) (4), (b) (6)	11 Nov 2020 16:29:57



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered '800'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:29:57

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:59:25**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered '1 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:29:57



US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:25
User closed query 'Per source notes, ConMed end date was 02Nov2020' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 03:17:57
Query 'Per source notes, ConMed end date was 02Nov2020' answered with 'Per note from 11/1/2020 from BB end date of Ibuprofen is 11/1/2020' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:00:46
User opened query 'Per source notes, ConMed end date was 02Nov2020' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 00:13:13
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 00:12:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered '1 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '1'	System	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '1'	System	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:09:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Dec 2020 00:11:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Dec 2020 00:11:15
User entered '804 (804)'	System	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 05:24:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 05:24:57
Data point term sent to Coder	System	24 Mar 2021 20:00:27
Coding entries removed.	(b) (4), (b) (6)	24 Mar 2021 19:59:35
Signature has been broken.	(b) (4), (b) (6)	24 Mar 2021 19:59:35
User entered 'Pfizer COVID-19 VACCINE (NON-STUDY EUA)' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 19:59:35
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:20:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:20:37
Data point term sent to Coder	System	17 Mar 2021 18:50:43
User entered 'Non-Study EUA COVID-19 Vaccine'	(b) (4), (b) (6)	17 Mar 2021 18:49:47



**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'COVID-19'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:59:35
User entered '0.3' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 19:59:35
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered '1'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:59:35
User entered 'mL (mL)' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 19:59:35
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:59:35
User entered empty; reason for change New Information	(b) (4), (b) (6)	24 Mar 2021 19:59:35
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47



**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:59:35
User entered '13 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 19:59:35
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'UN Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:59:35
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 19:59:35
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'UN Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User entered empty.	System	17 Mar 2021 18:49:47

**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User entered empty.	System	17 Mar 2021 18:49:47



**US3602111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:59:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:10:01
User entered empty.	System	17 Mar 2021 18:49:47

US3602111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:59:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:21:41
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:26:45

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'Visit 2 Day 29 (VISIT2)'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34



**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 16:47:34



**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34



**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:59:25

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '27 Oct 2020'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34



**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 16:47:34



**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:59:25

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:59:25

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered 'l'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:59:25

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34



**US3602111**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:10:37
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:52
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:25

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:33
User closed query 'Per CDM: Kindly consider to complete the End of study/study discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:20:56
Query 'Per CDM: Kindly consider to complete the End of study/study discontinuation form. Thank you.' answered with 'subject is continuing with study, however did not receive dose 2 due to being COVID positive' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:39:48
User opened query 'Per CDM: Kindly consider to complete the End of study/study discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:11:53
User entered '27 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 15:29:27
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Nov 2020 15:25:06

**US3602111**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:59:25**

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:33
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	30 Nov 2020 15:25:06

US3602111

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:25

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:01:33
User closed query 'Per CDM: Requery: Please consider to provide the AE log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 05:31:01
Query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	08 Dec 2020 05:30:58
Query 'Per CDM: Requery: Please consider to provide the AE log line number. Thank you.' answered with 'updated, however, the system generated query populated again. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 16:05:43
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	07 Dec 2020 16:05:20
User entered 'SAE USA-US079-2020-MRNA-1273-P301000003 (Log Line 7)' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Dec 2020 16:05:20
User opened query 'Per CDM: Requery: Please consider to provide the AE log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:18:55
Query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	07 Dec 2020 04:17:47
User closed query 'Per CDM: Please record AE record number. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:17:17

US3602111

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:25

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Query 'Per CDM: Please record AE record number. ' answered with 'Updated, however note new system generated query populated "Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct." Please close query on your end' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:12:30
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	04 Dec 2020 15:10:52
User entered 'SAE USA-US079-2020-MRNA-1273-P301000003' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Dec 2020 15:10:52
User opened query 'Per CDM: Please record AE record number. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:48:47
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 15:25:06

**US3602111**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:59:25**

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 17:13:56

**US3602111**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:59:25**

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:52:29
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	06 Feb 2021 17:13:56

US3602111

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:59:25

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:12:09
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:36
User entered 'RECEIVED NON-STUDY EUA Pfizer COVID-19 VACCINE on 13/Jan/2021 OUTSIDE OF THE CLINICAL TRIAL' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 20:13:36
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered 'RECEIVED a Non-Study EUA COVID-19 VACCINE OUTSIDE OF THE CLINICAL TRIAL' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:52:29
User entered 'received COVID vaccine outside of the clinical trial'	(b) (4), (b) (6)	06 Feb 2021 17:13:56



**US3602111**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:59:25**

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 17:13:56

**US3602111**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:59:25**

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 17:13:56

**US3602111**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:59:25**

**Date of death** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 17:13:56

**US3602111**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:59:25**

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:44
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 17:13:56

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'USA-US079-2020-MRNA-1273-P301000003'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:03
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Bindu'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:17
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Balani'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'NJ'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:21
User entered 'US'	System	06 Nov 2020 19:00:28

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '3'	System	24 Nov 2020 12:47:34
User entered '2'	System	21 Nov 2020 00:29:49
User entered '1'	System	06 Nov 2020 19:00:28

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'USA-US079-2020-MRNA-1273-P301000003'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:03
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Bindu'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:17
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Balani'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'NJ'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:25

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:21
User entered 'US'	System	06 Nov 2020 19:00:28

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '3'	System	24 Nov 2020 12:47:34
User entered '2'	System	21 Nov 2020 00:29:49
User entered '1'	System	06 Nov 2020 19:00:28

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:59:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:17:58
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
User entered '06/Nov/2020 19:00'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:59:25

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:17:58
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 19:00:28

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'USA-US079-2020-MRNA-1273-P301000003'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:03
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Bindu'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:17
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Balani'	System	06 Nov 2020 18:57:38



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'NJ'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:21
User entered 'US'	System	06 Nov 2020 19:00:28

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '3'	System	24 Nov 2020 12:47:34
User entered '2'	System	21 Nov 2020 00:29:49
User entered '1'	System	06 Nov 2020 19:00:28

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:59:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:17:58
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
User entered '21/Nov/2020 00:29'	System	21 Nov 2020 00:29:49

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:59:25

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:17:58
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:47:26
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 00:29:49



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'USA-US079-2020-MRNA-1273-P301000003'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:03
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Bindu'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:17
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Balani'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'NJ'	System	06 Nov 2020 18:57:38

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:21
User entered 'US'	System	06 Nov 2020 19:00:28

**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:59:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
User entered '3'	System	24 Nov 2020 12:47:34
User entered '2'	System	21 Nov 2020 00:29:49
User entered '1'	System	06 Nov 2020 19:00:28



**US3602111**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:59:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:17:58
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
User entered '24/Nov/2020 07:47'	(b) (4) System	24 Nov 2020 12:47:34

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:59:25

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:17:58
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:48:35
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 12:47:34